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Award Number: W81XWH-12-1-0524

TITLE: Psychosocial and Behavioral Factors Associated with Bowel and Bladder Management after SCI

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CONTRACTING ORGANIZATION: University of Michigan

REPORT DATE: October 2013

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2013	Annual	30September2012–29September2013

4. TITLE AND SUBTITLE

Psychosocial and Behavioral Factors Associate with Bowel and Bladder Management after SCI

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-12-1-0524

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of Michigan

Ann Arbor, MI 48109-1274

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
Persons with spinal cord injury (SCI) have associated bladder and bowel dysfunction, making this aspect of their care important to providers, researchers, and especially to those with SCI, their families and caregivers. While progress has been made in the area of bladder management, little has been done with respect to the psychosocial consequences of neurogenic bladder and bowel and their impact on quality of life (QOL). Loss of physical independence, community participation, respect, feelings of shame, lack of intimacy and sexuality are just some of the issues associated with neurogenic bladder and bowel. Adjusting to losses related to neurogenic bladder and bowel are especially relevant to military personnel for whom physical functioning is key. For veterans with SCI, these issues are compounded by difficulties associated with emotional wounds from combat, disruptions of family life and feelings of isolation. Two aims guide this investigation. The first is to identify risk factors associated with neurogenic bladder and bowel medical and psychosocial complications after SCI. The second aim is to determine the influence of bladder and bowel management and psychosocial and behavioral factors on QOL. To address these aims, we utilize a mixed method, multiple source approach to data collection and analysis. Qualitative interviews are used with 2 groups: persons with SCI (N=40) and caregivers (N=20). Additionally, 20 persons (10 SCI and 10 Caregivers) will participate in focus groups, making a total project sample of 80. These are supplemented by quantitative measures to evaluate the extent and severity of bowel and bladder related health problems. Statistical analyses of the quantitative data will target the structural constraints of individual behavior and the empirical linkages between and among the many factors. Qualitative analysis will include the construction of matrices to display coded text of narratives, facilitating pattern finding, mapping of text to the proposed conceptual model and thematic analysis. By evaluating a distinct military cohort, we will be able to address this question and propose treatment recommendations. Currently we have begun interviewing persons with SCI and their caregivers and testing them with a newly developed bowel and bladder inventory and a health behavior questionnaire. Data will be included in a presentation at the International Spinal Cord Society in October.

15. SUBJECT TERMS
Neurogenic bladder and bowel. SCI. Psychosocial and behavioral factors. Qualitative methodology. Mix methodology. Quality of life.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	139	19b. TELEPHONE NUMBER *(include area code)*

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Introduction

Bladder and bowel dysfunction is a critical issue for persons with spinal cord injury (SCI), their families, caregivers and clinical providers.[1,2] Persons with SCI have associated bladder and bowel dysfunction, making this aspect of their care important to providers, researchers, and especially to those with SCI, their families and caregivers. While progress has been made in the area of bladder management after SCI, little has been done with respect to the psychosocial consequences of neurogenic bladder and bowel and their impact on quality of life (QOL). Loss of physical independence, community participation, respect, feelings of shame, lack of intimacy and sexuality are just some of the issues associated with neurogenic bladder and bowel.[3] Adjusting to losses related to neurogenic bladder and bowel are especially relevant to military personnel for whom physical functioning is key. For veterans with SCI, these issues are compounded by difficulties associated with emotional wounds from combat, disruptions of family life and feelings of isolation.[4]

Two aims guide this investigation. The first is to identify risk factors associated with neurogenic bladder and bowel medical and psychosocial complications after SCI. The second aim is to determine the influence of bladder and bowel management and psychosocial and behavioral factors on QOL. To address these aims, we utilize a mixed method, multiple source approach to data collection and analysis. Qualitative individual interviews are used with two groups: persons with SCI (N=40) and caregivers (N=20). Additionally, 20 persons (10 SCI and 10 caregivers) will participate in focus groups, making a total project sample of 80. These are supplemented by quantitative measures to evaluate the extent and severity of bowel and bladder related health problems. Statistical analyses of the quantitative data will target the structural constraints of individual behavior and the empirical linkages between and among the many factors. Qualitative analysis includes the construction of matrices to display coded text of narratives, facilitating pattern finding, mapping of text to the proposed conceptual model and thematic analysis. By evaluating a distinct military cohort, we are able to address this question and propose potential treatment recommendations.

The first year of this project included the completion of many activities and tasks such as establishing the project infrastructure, hiring personnel and providing training to investigators and consultants. We have completed the IRB process for both facilities: the University of Michigan Health Systems and the Ann Arbor VAMC and received approval from the Department of Defense (DoD). A manual of operations and interview guidelines were developed and distributed and interviews and testing has begun with the UMHS site. Preliminary data will be included in a presentation to be made at the 52nd annual scientific meeting of the International Spinal Cord Society (ISCoS) in October 2013.

Body

The body of this report is a narrative serving to outline the tasks and work performed during the first year of the project. It is divided into six sections, as per our approved Statement of Work.

1. Administrative tasks

Tasks include those being performed at the different sites as well as project start-up and recruitment of personnel; coordination with work sites; submission of IRBs; orientation of advisory or steering committee members; maintaining relationships with Department of Defense CDMRP and SCI program representatives, grant administration and coordinating and overseeing consultants' involvement across sites. Three sites are involved: 1) University of Michigan/Dept. of Physical Medicine and Rehabilitation (lead site/PI: Tate); 2) VA Ann Arbor Healthcare System (site PI: Diponio); and Michigan Paralyzed Veterans of America (site contact: Michael Harris). This third site serves exclusively the function of recruitment, dissemination and guidance to project activities. Mr. Michael F Harris, Executive Director of MPVA has agreed to serve on the Steering Committee or Advisory Board for this project. Research will be conducted primarily by the first two sites listed. (Months 1-36)

1a. Project start-up activities (Months 1-6)

During the first six months of the project, we began the process of recruiting a Research Associate/ Study Coordinator for the project. A position announcement and job description were posted and from an initial pool of approximately 40 candidates, seven candidates were interviewed and screened. Mr. Edward J. Rohn, MA. was selected as the preferred and most qualified candidate. Mr. Rohn is a medical anthropologist and PhD Candidate at Wayne State University, with years of qualitative interview experience and a background working on large grants. Mr. Rohn serves as study coordinator and has been given administrative duties to design, implement, and oversee much of the day-to-day functioning of the project, as well as recruitment, data collection, and pending data analysis. He has done an excellent job in assisting both site PIs. Mr. Rohn works very close with Dr. Tate.

All sites were notified of the grant award on September 2012. A first meeting took place on November 2012 among all project investigators, staff and consultants to review the proposed activities and organize a plan of action to be coordinated between the two sites.

Following a work plan developed by the PI in conjunction with team members, job descriptions for consultants and research staff were also developed. At the November meeting, the PI provided an in-depth orientation to the project, including its objectives, methodology, roles, and work plan. Further, a post-doctoral research fellow, Dr. Andrea Nevedal, joined the project. Skilled in qualitative methodology, Dr. Nevedal was placed in charge of developing the qualitative interview guides in conjunction with Dr. Duggan, project consultant. .

Project investigators, research staff and grant administrators met to discuss the implementation of an action plan to begin grant activities. A subaccount was set up with Urology to cover Dr. Cameron's effort. Dr. Werner, Chief of PM&R at the VA approved all personnel and research resources from the VA site. Investigators at UM included the following faculty: Drs. Tate, Kalpakjian, Cameron and Rodriguez and Mr. Forchheimer, for his role overseeing the quantitative analyses. At the VAMC, Drs. DiPonio and Roth were confirmed as key VA personnel involved in this project. SCI patients are seen in Dr. DiPonio's clinics and interviewed by Dr. Roth, Psychologist with assistance of Mr. Roth, study coordinator. Advisory board or Steering Committee members were contacted and asked to confirm their interest in

participation. They were sent information about this project and a meeting is planned for Spring 2014. Members include: Michael F Harris, MPVA Executive Director and someone with a SCI himself; Sandy Loyer, past UM-SCI social worker for over 20 years and currently a consultant to Department of Army to assist returning soldiers and their families with adjustment issues; Dr. Mark Luborsky, a medical anthropologist with extensive experience in qualitative methods and Dr. Cathy Lysak, Associate Professor at Wayne State University with an occupational therapy background and experience in SCI care and research and also an experienced qualitative methodologist. All members have confirmed their participation. Drs. Werner and Chiodo were dropped from the original list of potential members since the project already has a strong physician representation among Drs. DiPonio, Cameron and Rodriguez. Dr. Rodriguez and DiPonio see SCI patients at their clinics at UMHS and VA and Dr. Cameron treats those with SCI with bladder problems at her UM-Urology clinic. She too is familiar with the VAMC in Ann Arbor where she served as a fellow initially.

Necessary supplies and equipment were purchased, including software for qualitative data analysis (NVivo), audio recording equipment for interviews, general office supplies, storage media and batteries.

1b. IRB and other regulatory approvals required by UM, VA and CDMRP (Months 2-6)

Drs. Kalpakjian and Nevedal met with Mr. Doug Feldman, IRB Coordinator for the VAMC to begin the process of establishing the VA IRB. Two separate IRBs were submitted and the University of Michigan IRB was quickly approved. The VA IRB process involved considerable extra work to assure the site of the security of the data being collected, to screen the staff assigned to work on the VA portion of the study, and to conform all documentation to specific VA IRB requirements. These delays resulted in the final approval coming in July 2013, as opposed to the anticipated May 2013. Coordination between the two sites further delayed the final approval of the project by an additional month. Final approval to begin research activities came from the DOD 24 July 2013.

Both the certificate of environmental compliance and all safety program documents are completed, being finished and submitted prior to the award being made.

1c. Submission of research reports to the Department of Defense (Months 11, 24 and 36)

The present annual report stands as the above research report for Month 11. Future reports are pending. Further, all quarterly reports were submitted as required, on 31 Dec 2012, 31 March 2013, and 30 June 2013. A fourth quarterly report was submitted 30 Sept 2013, but we were told it was unnecessary since this information is covered in this annual report.

1d. Consultants agreements/scope of work and timelines confirmed (Months 1-3)

Dr. Tate provided each consultant with a job description and a letter of agreement about their role and tasks in the project. Payments are based on accomplished tasks. Dr. Duggan was paid on March 2013 for her work on providing training to interviewers. Ms. Roller was paid for her role in conducting a caregiver interview.

1e. Establishment of DSMB (Data Sharing and Management Board) (Months 3-6)

The project is not a clinical trial or intervention study and does not require a DSMB.

1f. Contract with transcription services (Months 3-4)

Data transcription services were secured for the UM arm of the study. A private company was retained (Datagain) with UM IRB consent, signed non-disclosure agreements, and a payment system established through our grant administration office. This task took longer than expected and was completed in July (Month 10). VA transcription services are still pending. The VA has strict requirements on who can work as a transcriptionist when the research involves VA patients. Currently, there are only two private individuals whom the VA will allow to conduct this work and negotiating their contracts has proven administratively difficult. We anticipate resolving these difficulties within the month (Month 13).

1g. Payment for subject fees for participation (Months 6-30)

As data collection began in August (Month 11), subject fees have been paid as participants complete data collection activities. This task will continue throughout the length of data collection.

2. Research Design

Tasks include development and refinement of conceptual steps for both the qualitative and quantitative aspects of the study; refinement of the semi-structured individual and focus group interviews for SCI participants and caregivers; review of measures; refinement of diary format and summary forms; develop database and data sharing plan. (Months 1-10)

2a. Development, refinement and review of interviews and study measures (Months 1-3)

Revisions to the qualitative interviews continued into June 2013 (Month 9). This process of revision resulted in a better data collection instrument. Mr. Marty Forchheimer, our quantitative expert and statistician, finalized the design of quantitative measures He revised the existing Bowel and Bladder Treatment Index (BBTI) into a short form (BBTI-SF) and attempts were made by the team to clearly mesh the questions from the qualitative and quantitative data collection tools, to provide the opportunity for integrative data analysis and discussion. These instruments were approved by both the UM and VA IRBs, as well as part of the final approval from the DoD, prior to beginning data collection.

2b. Pilot of measures and interviews with SCI participants and caregivers (Months 3-4)

Pilot interviews were conducted with three SCI volunteers and one caregiver volunteer with the strict goal of refining our interview guides and data collection tools in preparation for a full roll-out in August (Month 11).

2c. Refinement of Bladder and Bowel Diary format and reporting forms (Months 3-5)

This activity was dropped as it was felt that it would duplicate work being done already by the UM SCI Model System program. This was discussed in a letter to the sponsor addressing reviewers concerns to avoid duplication of efforts between this newly funded project and the UM SCI Model System project funded by National Institute on Disability and Rehabilitation Research.

2d. Development of databases in word, Excel, SPSS, and NVivo (Months 5-10)

Excel spreadsheets were developed for the purpose of tracking potential participants for the purpose of contacting and scheduling interviews. REDCap is being used for the collection and recording of measures data, as well as the tracking of other research tasks relevant to each participant (e.g. payments processed, audio files transcribed, and thank-you notes sent). SPSS and NVivo databases have not been completed, and will be developed as more data becomes available and data analysis can begin in earnest.

2e. Review of plans for data sharing and dissemination of products (Months 7-10)

Because the project start date was delayed due to VA IRB issues this activity was not completed. We will address these plans in Year 2. The only planned activity for preliminary data sharing and dissemination is the presentation to take place in October 2013 (27-30) at the ISCoS meeting mentioned earlier.

3. Recruitment related tasks

Tasks include development of a plan for recruitment to include all sites with special attention given to the VA and MPVA. The U-M SCIMS database will serve as another source of recruitment as will our SCI Registry and community-based agencies. (Months 5-30)

3a. Send letters of invitation, phone contacts, informed consents and conduct eligibility verification with participants; scheduling interviews and focus groups (Months 6-25)

Beginning in August (Month 11), we sent letters to a list of 14 potential SCI participants from UM provided by the SCI Registry. These letters provided the potential participants a window to opt-out of further contact. No participants opted-out of being contacted, and recruitment efforts by telephone began in earnest two weeks after the letters were sent. As of October (Month 13), six of these participants were found to be eligible and interested; they were subsequently consented and interviewed. Four were either uninterested or ineligible. Attempts to contact four potential participants from the initial 14 are still being made. One additional SCI participant was identified through physician referral

Beginning in September (Month 12), we sent letters to an additional 14 potential SCI participants from the VA, provided by the caseload of co-investigator and current VA PI, Dr. Lisa DiPonio. These letters provided the potential participants a window to opt-out of further contact. No participants opted-out of being contacted. Due to unforeseen complications around our IRB approval (related to which staff members are permitted to conduct interviews), telephone contact with these potential participants has been delayed and will begin this month. An amendment is currently in process with the VA IRB to add the study coordinator to interviewing activities. Interviews will begin this month (Month 13) with currently approved staff; with the hopes of adding Mr. Rohn as an additional interviewer to facilitate more rapid data collection.

Two of the six SCI participants referred their caregivers to us for inclusion in our sample. One has been contacted and agreed to participate in the study. The other was contacted and declined to participate. Additional caregivers will be recruited in the same way to meet target numbers. If these target numbers appear to become a challenge to meet, additional strategies for referring caregivers have been identified – including working with physicians on the project to identify caregivers and recruitment through PVA.

Recruitment efforts will easily capture those participants whose SCI-related injury occurred more than 10 years ago. This is a large population. The arm of the study involving new injuries (less than 1 year since injury) has been a larger recruitment challenge and necessitated additional recruitment strategies. Co-investigators, Dr. Anne Cameron and Dr. Gianna

Rodriguez have graciously assisted the project by agreeing to identify patients on their case load who fit our recruitment criteria for this new injury category. So far, we have identified 17 additional potential participants to be sent letters this month with hopes of finding 10 newly injured participants (less than 12 months since injury) who agree to participate in the study. We published an IRB-approved recruitment posting on the University of Michigan Spinal Cord Injury Model Systems website (http://www.med.umich.edu/pmr/modelsci/news/index.htm). The SCIMS and PVA quarterly newsletters will include recruitment flyers as well. We have posted approved flyers in both the UM Urology and UM Spinal Cord clinics.

Please refer to Tables 1-3 in the Supporting Data section for a more detailed breakdown of our recruitment efforts. Recruitment will continue until all subjects are recruited, enrolled and interviewed or until the first quarter of Year 3, as planned.

3b. Organize interview schedules and focus group activities with the sites (Months 6-25)

Interviews are being scheduled between the participant and staff member(s) assigned to interview them. This process is working well and allows the staff and participants flexibility in making and keeping appointments. Focus group planning has not yet begun and is scheduled for the end of the second year and into the beginning of the third. Interviews are scheduled to continue until the third quarter of Year 3 as necessary.

4. Data collection and data processing tasks

Tasks include conducting interviews with the 80 participants (persons with SCI and caregivers); conducting focus groups; processing qualitative and quantitative data and data entry (Months 6-33). Sixty individual interviews will be conducted, as well as 20 participants will take part in focus groups. Focus group sessions will be transcribed and data analyzed accordingly.

4a. Train interviewers, conduct individual interviews, administer measures (Months 6-30)

Beginning on 26 June 2013 (Month 9), we held a large training meeting to foster a shared sense of purpose in data collection, a clear shared sense of the goals and aims of the project, followed by a second qualitative and quantitative training session for all the interviewers (9/16/13). The skill sets of all interviewers were tailored to the tasks at hand – with those with deeper qualitative and interviewing skills assigned to conduct qualitative interviews and those with a background in quantitative measures to assist participants in completing questionnaires. Staff and trainers reviewed the training manual and learned how to access information needed to conduct interviews and complete data collection. Dr. Anna Kratz, Assistant Professor in Physical Medicine and Rehabilitation and also a qualitative researcher joined the project (5% effort) in the Spring of 2013 to assist with interviewing coding and reliability as well as data collection. This was possible since the additional research assistant, Ms. Connie Pines, a trained nurse with personal SCI experience, did not require a permanent appointment and could be appointed on a temporary status. This allowed us to stay within the projected and approved budget. Ms. Pines assists with caregivers' recruitment and conducts quantitative assessments.

Beginning in September (Month 12), data collection began with participants in the UM SCI group. The system developed by the study coordinator involves a two-part interview – one qualitative and face-to-face, with a telephone follow-up to complete the questionnaire. Teams of interviews – one qualitative and one quantitative – have worked well together in completing these first few interviews. The study coordinator has conducted both halves of the interview on one occasion to maintain a thorough understanding of the process.

Data collection will continue until the required sample size has been attained. This should be completed within the next 12 to 18 months; on schedule, per our statement of work.

A comprehensive Manual of Operations was developed and implemented by our study coordinator. This manual exists in PDF format and is in the possession of all interviewing staff members. This document keeps all the most up-to-date IRB-approved documents for the project in one place, to assure ease of access and compliance with IRB requirements. Please see Appendix 1 for the full manual.

4b. Have SCI participants complete 2-week Bowel and Bladder Diaries and Summaries (Months 6-31).

This activity was dropped as it was felt that it would duplicate work being done already by the UM SCI Model System program. This was discussed in a letter to the sponsor addressing reviewers concerns.

4c. Enter data based on subject diaries into SPSS database (Months 7-32)

N.A., see information above.

4d. Mail audio files to the transcription services (Months 9-31)

As detailed earlier, we have secured transcription services for the UM arm of our study. This arrangement has functioned very well, with a quick turnaround and high level of accuracy. Transcription services with the VA are still being worked out, and we anticipate resolution soon.

4e. Review interview transcripts in Word database, clean data, enter narratives into the NVivo database, code qualitative interviews, conduct inter-rater reliability for coding; score all quantitative measures and enter those into SPSS database (Months 10-33)

All completed transcripts (N=4) have been checked for accuracy and cleaned of all remaining identifying information. We have scheduled a coding meeting with a core of the research staff to begin development of a code book, discuss how coding will proceed, and to begin practicing coding procedures. Transcripts will be loaded into NVivo for this practice, but not before. Coding will proceed on an on-going basis following this meeting. Inter-rater reliability will be one goal of this coding practice, checking across the same transcripts to see if the coders code similar passages with the same codes. The proposed tree node application structure for coding is contained in the original grant application in the project narrative (Figure 2). Quantitative measures are scored on an on-going basis, and will be entered into SPSS in the future, when more data is available and data analysis is set to begin.

4f. Have focus group audio files transcribed, enter narratives into NVivo database and code interviews (Months 22-33)

Focus groups are not scheduled to take place until the end of the second year. This task will be completed following completion of the focus groups.

5. Data analysis and evaluation tasks

Tasks include mixed method analysis and triangulation of data. Includes evaluation of activities related to the conduct of the investigation itself (Months 11-35).

5a. Prepare basic statistics to describe samples and their scores; perform statistical analysis and qualitative analysis of transcripts for themes and patterns (Months 11-34)

These data analysis tasks are in the planning stages. Due the set-backs of IRB approvals, we have not amassed enough data to begin analyzing in earnest.

5b. Conduct triangulation of qualitative and quantitative data sets (Months 15-34)

A meeting is planned for November 2013 (Month 14) with project investigators, consultants and staff members who have experience and expertise in mixed method analysis to begin planning for this data analysis task.

5c. Review data regularly to evaluate coding schemes, discuss patterns emerging, and findings from the quantitative analysis (Months 13-33)

Team members have already begun discussing preliminary patterns that seem to be emerging from the limited current data set. However, this activity is only preliminary and mostly gauged towards determining that the qualitative interviews are capturing the necessary quality of life information we require to address our aims. As more data is collected, this research task will become more involved, including regular meetings between staff members to maintain a unified sense of purpose moving forward. Dr. Duggan will play an important role in providing guidance to this process.

5d. Review focus group data and integrate it with other qualitative data (Months 20-33)

As focus groups have not yet been conducted, this task is yet not completed.

5e. Analyze data from the Bowel and Bladder Diaries, including conduct of linear mixed models (Months 24-34).

N.A. as detailed above.

5f. Conduct regular meetings to discuss data interpretation and evaluation (Months 11-35)

The entire project meets quarterly for updates and to roll-out and reinforce procedures. These meetings have included reports on recent collection – including brief outlines of informal findings from individual interviews. Further, the PI and study coordinator meet regularly, alone and with interview staff, to discuss progress on the data collection and interviewers initial impressions of the type and quality of data being collected. More formal meetings regarding data analysis will occur when data analysis begins. The study coordinator also meets with other SCI staff to discuss recruitment through SCI clinics and SCI Registry and data management on a regular basis.

6. Dissemination and data sharing tasks

Tasks include discussions with focus groups at U-M, VA and MPVA, presentations at the AACIL and national meetings, website links to project activities, products and findings. We will

use the existing U-M SCIMS website with links to the VA and MPVA sites to distribute this information. (Months 10-36).

6a. Appointment of a DSMB and development of a data sharing plan (Months 5-10)

The project does not require a DSMB.

6b. Development and dissemination of findings in lay language to persons with SCI, their families and caregivers through a second presentation at the AACIL, consumer brochures and fact sheets. These will be distributed through websites, presentations and meetings (Months 25-35).

As this is planned following the completion of data collection and analysis, this task has not yet begun. Relationship with AACIL is in place and they are eager for us to present.

6c. Presentations at DoD and CDMRP sponsored meetings (Months 11-36)

N.A. – as these have not yet occurred.

6d. Preparation of final report and manuscripts (Months 15-36)

Final report will be prepared following the completion of the project. Because of initial project start up delays related to obtaining IRB approval at the Ann Arbor VA we anticipate that the project will be extended beyond the original ending date to accommodate the conclusion of project tasks and activities and writing of the final report.

Project team members have begun strategizing potential publications, to be completed as more data is collected and analyzed. An initial publication may follow the presentation to be made this October at 52nd Annual Scientific Meeting of the ISCoS on issues of bowel and bladder and their effects on quality of life. A second publication may describe the coding schema and reliability procedures.

Key Research Accomplishments

- Six participants have completed the data collection process, with recruitment on-going and providing many leads for additional interviews. This data will be included within the presentation ISCoS – (see below). Table 4 summarizes some preliminary data suggesting themes such as environmental accessibility, physical capacity, societal participation, time management and planning, and employment, all which are viewed as affecting quality of life after SCI with loss of bladder and bowel functions. See Table 4 in Supporting Data section.

- Thematically, these interviews focus heavily on quality of life while managing neurogenic bladder and bowel, with particular emphasis on:

    - Sexuality and the challenges of establishing and maintaining intimacy. Participants have mixed results in this area. Some have creative ways of working around the problems while others have abstained from any form of sexuality whatsoever since their injury.

    - Obligations – including work and home life – have often been challenging as well, leading half of respondents to begin their own businesses or free-lance work from home. These career paths seem to provide a strong sense of self-worth, but also a lack of normative life patterns.

    - Social activities are greatly curtained by the absence of accessible toilet facilities at the homes of friends. Even in public, with handicap accessible bathrooms, multiple subjects commented on how their chairs will not fit in stalls and still allow them access to the toilet. It's easier to stay home.

Reportable Outcomes

Two poster presentations have been accepted for the 52nd Annual Scientific Meeting of the International Spinal Cord Society in Istanbul, Turkey, October 28-30, 2013. These presentations feature preliminary data in the first and a description of the development of one of our quantitative measures, the Spinal Cord Injury Bowel and Bladder Treatment Index (BBTI), in the second.

1. The effects of bowel and bladder dysfunction on quality of life after SCI

Objective: To examine the effects of bowel and bladder management and complications on quality of life after spinal cord injury.
Materials-Methods: This study uses a mixed model to determine the effects of neurogenic bowel and bladder management, related complications, health behaviors and relationship with providers on the quality of life of persons with SCI. Subjects will be interviewed with the newly designed BBTI (Bowel and Bladder Treatment Index which is based on the international datasets) and information will be collected also on quality of caregiver support, patient-provider working alliance, adherence to treatment and health behaviors. Quality of life (QOL) is being assessed using the Life Satisfaction Index, and SCI-QOL, a newly developed measured using PROMIS and Neuro-QOL data banks. Qualitative interviews are being conducted also to provide additional information about subjects' feelings and problem solving skills.
Results: Very few studies have focused on the impact of neurogenic bladder and bowel on QOL or psychosocial and behavioral factors associated with bladder and bowel dysfunction. Qualitative findings so far clearly illustrate the devastating effects of loss of function on people's self-esteem and sense of dignity. These findings also show that persons with SCI often have difficulty maintaining social relationships due to fear of accidents. For women with tetraplegia bladder management is particularly challenging.
Conclusion: Studies are needed to design interventions to assist persons with SCI with managing bowel and bladder dysfunction while developing strong coping skills and healthy behaviors to address these important issues while minimizing their effects on QOL.

Keywords: bowel, bladder management, quality of life

2. Development of interview forms for the international spinal cord injury datasets for bowel and bladder

Objective: To develop a clinical interview version of the international SCI datasets for bowel and bladder based on the bowel function core data and extended dataset and lower urinary tract dataset.
Material-Methods: The international SCI datasets were developed to be completed by clinicians after patient assessments. These datasets could be more widely used if designed as clinical interview tools to collect data directly from patients and by complementing it with medical records review. The interview measure – Bowel and Bladder Treatment Index (BBTI) – was developed with input from physicians, psychologists, researchers and therapists. Researchers reviewed the item content of these datasets and developed questions under each item. Pilot tested was conducted and revisions made accordingly to also incorporate patient feedback.

Results: The revised BBTI is currently being used with a large sample of persons with SCI. A short form (BBTI_SF) was developed for a project funded by the Department of Defense. Validation consists of cross-referencing responses across measures of similar content and by evaluating the degree responses correspond to information from the respondents' records.
Conclusion: The development of these interview guides and scoring profiles will assist clinicians and researchers in obtaining consistent, reliable and easy to use information about bowel and bladder care after SCI. This information will promote efficiency in managing these two important issues affecting the quality of life of persons with SCI. Similar tools can be developed for other datasets.

Keywords: Bowel, bladder, datasets.

Conclusion

With six interviews completed, we've begun to grasp some of the thematic patterns that may prove evident in the entire sample. We've finalized our procedures such that the remainder of data collection should be much smoother. We are in the planning stages of a number of publications to discuss the methodological challenges we faced, limited literature on this area of inquiry (in particular on military culture and the impact of SCI/NBB), and the findings of our data. We anticipate significant progress in the year to come.

Overall, the first year of our study has been a successful exercise in perseverance. We navigated the requirements and delays of multiple IRBs (in particular, delays at the VA), the implementation of a complicated mixed-methodological approach, and the establishment of the complex infrastructure necessary to complete the project. We are poised and ready; moving forward into a highly fruitful Year Two.

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Supporting Data

Table 1

SCI Recruitment and Data Collection by Overall Neurologic Level of Injury					
Sample Arm	**Neuro Level**	**Identified**	**Screened**	**Completed**	**% Complete by Neuro Lvl**
UM SCI >10 years (N=10)	Para (N=5)	7	6	2	40%
	Quad (N=5)	8	8	5	100%
UM SCI <1year (N=10)	Para (N=5)	3	0	0	0%
	Quad (N=5)	14	0	0	0%
VA SCI Long (N=20)	Para (N=10)	7	0	0	0%
	Quad (N=10)	7	0	0	0%

Table 2

SCI Recruitment and Data Collection by Sex					
Sample Arm	**Sex**	**Identified**	**Screened**	**Completed**	**% Complete by Sex**
UM SCI >10 years (N=10)	Male (N=7)	10	6	5	71%
	Female (N=3)	5	8	2	66%
UM SCI <1year (N=10)	Male (N=7)	10	0	0	0%
	Female (N=3)	7	0	0	0%
VA SCI Long (N=20)	Male (N=20)	14	0	0	0%
	Female (N=0)	0	0	0	0%

Table 3

Caregiver Recruitment and Data Collection by Research Site					
Sample Arm	**Site**	**Identified**	**Screened**	**Completed**	**% Complete**
Caregivers (N=20)	UM (N=10)	2	1	0	0%
	VA (N=10)	0	0	0	0%

Table 4

Subject	Quote
50-year-old male with T3 paraplegia	Well, the first thing that pops in my head is that if visit someone's home chances are pretty good that I can't use their bathroom, so my social activity is limited by if I can get into somebody's house at all, I guess. And then on top of that not being able to use the bathroom is usually an issue. And there are other venues where there might be some event that I'd like to go to, but I can't because I either can't get in or… Like I was at a tailgate for a football game a few weeks ago and I had to use the bathroom, so I had to leave because there wasn't any facility that I could use around there.
35-year-old male with T3 paraplegia	My bowel program in the morning can go you know, from lasting an hour to like three hours depending on what my diet's been, how I'm feeling and stuff like that. I don't always have that like you know, for sure feeling that I'm done. So I like to hang out and not rush things if at all possible. And then at work if I have problems and stuff, there's times when I've had accidents where I've just had to like, it's like "Hey, I gotta go," and just like leave and not really give much of an explanation or anything because of embarrassment. And you know, some employers are kind of cool with it and some employers are like "No way, we can't have somebody doing that." So it's, you know, that's kind of a pain in the butt. But so I figured it was a lot easier just trying to learn to do freelance stuff and work at home.
64-year-old male with C4 quadriplegia	I just deal with it. The bowel I take care of every three days in the morning. Make sure it's all taken care of and go about my day. When I get the urge for bladder relief I just tell them "It's time for a cath." They'll find a private room or go back to the van.
30-year-old male with C5 quadriplegia	I personally haven't had a bowel accident in over a year, though the last time was pretty inconvenient, since it was at a hotel. We were supposed to visit my family – we were driving to visit family in the Jersey Shore and we stopped in Hershey, Pennsylvania. We stopped there for the night and we were thinking we'd go tour the chocolate factory the next morning and drive the rest of the way that afternoon. But I had a bowel accident and all that cleanup, by the time that was over with no one really wanted to do anything but just finish the drive, so we killed that plan.
43-year-old male with C5 quadriplegia	I am the guy that uses family and girlfriends and friends and nephew. I mean I'm older, I got nephews showering me and you know, we're best buddies, but again that's my life. It's what happens. So I deal with it and I get it done, but it's again it's probably the biggest thing that we conquer in this position. I feel sexuality issues aren't even as bad as this bowel and bladder, because it's – it never goes away. It never stops. You can push sex away. This is always there. So it never – you always have to – you're facing it. It never goes away. No. Some things you can just get away from, push away, and they're a little out of sight, out of mind. This never goes away. It just doesn't.
64-year-old female with C6 quadriplegia	I do need help because I cath from the chair or either I have to get in bed. I always tease the guys because I say all you have to do is just zip and clip, whereas women the way that we're built I have to take off my clothes and I wear pants a lot, in order to get … to what needs to be done. So it's difficult for me unless I've got a bed somewhere or unless I'm at somebody's house and I can use their bed or unless I can get someone to do it for me from the chair. But it hasn't stopped me from doing what I'm doing. It's just a matter of planning and… You know, I just went camping with a group of people and I made sure there was going to be someone there to help me cath, so they had attendants and so forth.

Appendices

- See Appendix 1 – Manual of Operations – beginning on the next page

DOD RESEARCH PROJECT

Psychosocial and Behavioral Factors
Associated with Bowel and Bladder Management after SCI

DATA COLLECTION PROCEDURES MANUAL

Prepared by:
Edward J. Rohn, Study Coordinator

Updated:
October 9, 2013

CONTENTS

1. RECRUITMENT & SCREENING PROCEDURES

1. Potential SCI subjects are identified in one of three main ways:
    a. Databases (registries and physician patient lists)
    b. Advertising (flyers, websites, and newsletters)
    c. Referrals (direct physician referrals, other participants, allied sources – Connie)

2. Potential subjects are sent recruitment letters by the relevant registry's manager (Rachel Hartwig @ UM and Amanda Raine @ VA) – each site has own IRB-determined opt-out window.
    a. UM potential subjects have a two-week window to opt-out.
    b. VA potential subjects have a three-week window to opt-out.

3. Once the allotted time windows have expired, the contact information of those that did not opt out will be forwarded from the relevant registry manager to the DoD study coordinator (Rohn).

4. Study coordinator (Rohn) will assign unique Subject ID#s to each potential subject, following in sequential order from the last known Subject ID#.
    a. UM SCI subjects will be labeled as – UM-0XX (for example, UM-001, UM-025, etc).
    b. VA SCI subjects will be labeled as – VA-0XX (for example, VA-001, VA-032, etc).
    c. UM Caregivers will be labeled as – UM-1XX (for example, UM-101, UM-109, etc.)
    d. VA Caregivers will be labeled as – VA-1XX (for example, VA-101, VA-109, etc.)

5. Study coordinator (Rohn) will call potential subjects to complete the relevant oral recruitment script and relevant screening form. Will recruit additional help in this as needed.
    a. There are specific oral recruitment scripts and screening forms for each site (UM, VA)
    b. Also, different oral recruitment scripts and screening forms for each arm (SCI, Caregiver)

6. Enrollment
    a. If subject passes the screening and agrees, they can considered to be "enrolled".
    b. Those that do not pass screening, but want to participate, should be brought the PI (Tate, DiPonio) for final decision on enrollment.

7. Study coordinator (Rohn) will assign one or two interviewers to each subject, depending on the subject, project roles, and current workload. See attached Interview roles chart for details:

8. Study coordinator will provide interviewers with Subject ID#s. These can be used to acquire contact information, medical data relevant to injury (if applicable), and the findings of the screening procedure.
    a. For UM subjects, REDCap will provide all the relevant contact information.
    b. In cases where someone does not have access to REDCap, the study coordinator (Rohn) can provide this information in a secure correspondence (telephone or direct handoff).
    c. For VA subjects, all contact information will be stored on the secure VA server in an Excel spreadsheet.

9. See attached forms for your convenience. Forms are also stored on the shared drive (folder labeled “DoD Project 2012”)

ORAL RECRUITMENT SCRIPT HUM68800

Hello, my name is XXX and I am calling from the University of Michigan Department of Physical Medicine and Rehabilitation. I want to tell you about a new study we are doing to see if you would be interested in joining. Would that be OK?

IF NO, thank them for their participation and hang up.

IF YES, proceed to the following:

We are conducting research about how neurogenic bladder and bowel in people with spinal cord injury affect quality of life and other things like mood, going out into the community and taking care of bowel and bladder dysfunction. The study is asking persons with SCI (civilians and veterans) and caregivers of someone with spinal cord injury about their experiences in managing bowel and bladder dysfunction. Would you be interested in joining this study?

IF NO, thank them for taking the time to hear about it and hang up.

IF YES, proceed to the following:

FOR EVERYONE: The study has two parts. The first is a one-on-one interview, which can be done over the phone or in person, for example at your house or at the clinic – talking in depth about issues such as the kinds of problems you experience with bowel and bladder and how these affect your independence, coping with problems, or how taking care of bowel and bladder functions affects intimate and family relationships. The interview will take 60 – 90 minutes to do.

FOR SCI ONLY: You will also complete a series of questionnaires about your mood, the quality of care you get, and you bowel and bladder program and any specific problems you may have. That should take another 60 – 80 minutes.

FOR EVERYONE: Next, if you choose to do so, you may also participate in a focus group, on a different day, which will take 60 - 90 minutes to complete; there will be a focus group for people with spinal cord injury and a separate one for caregivers. The focus groups will be held in Ann Arbor in a place that is accessible and easily reached by the highway or other main roads.

Does this sound like something you would be interested in doing?

IF NO, thank them and hang up.

IF YES, proceed to the following.

If you have time, I have a few more questions for you. These are more specific and will help me confirm your eligibility for the study. Would it be OK for me to ask you those questions now?

IF YES, proceed to the SCI SUBJECT SCREENING FORM or the CAREGIVER SUBJECT SCREENING FORM, as appropriate.

IF NO, proceed to the following.

Thank you for agreeing to join this study! When is a good time to contact you so we can go through the questions in order to confirm your eligibility? Is this the best number to use to contact you again?

SUBJECT ID#: **DATE:**

SPINAL CORD INJURY SUBJECT SCREENING FORM HUM68800

DEMOGRAPHICS (from SCI registry/medical record):

SEX: Male Female TIME SINCE INJURY:

WILLING TO TRAVEL: YES NO LEVEL OF INJURY/ASIA SCALE:

Use the following script when screening a potential participant.

1. Can you tell me about the cause of your injury?

Listen to their brief response.

2. Due to your SCI, do you have any problems with your bladder and bowel functions?

Listen to their brief response.

3. Do you have a caregiver, someone who works with you to meet at least some of your needs?

Listen to their brief response.

4. Are you able to travel to Ann Arbor to meet with one of our interviewers for this study?

IF YES, skip to Question 6.

IF NO, proceed to the following.

5. We may be able to arrange for one of our interviewers to come to your home and interview you there. Would that be OK?

IF YES, proceed to the following.

IF NO, ask if there is an alternative since neither Ann Arbor nor their home seems to work for them.

6. Do you have any questions for me about the project?

Answer any questions. Once complete, ask them to hold a moment and proceed to the following page.

SUBJECT ID#: **DATE:**

SPINAL CORD INJURY SUBJECT SCREENING FORM HUM68800

Address the following from your point of view:

DO NOT ASK THIS QUESTION OF THE POTENTIAL SUBJECT – SCREENER ANSWERS HIM/HERSELF:

Potential subject has the ability to express themselves regarding their experiences: YES NO

IF YES, proceed to the following.

Thank you for your time and for answering my questions. I feel you would be a good fit for our study and someone will contact you soon to set up an appointment to conduct the interview. Is the phone number I called today the best way to reach you?

Record their preferred phone number and proceed to the following.

We have both male and female interviewers. Do you have a preference for your interview?

Circle one: Male Female No preference

Assure them that someone will be contacting them soon to schedule an interview, thank them again for their time, and hang up.

IF NO, proceed to the following.

Thank you for your time and for answering my questions. I would like to discuss your case with our research team. We will contact you with a decision regarding your eligibility within the next two weeks. Is the phone number I called today the best way to reach you?

Record their preferred phone number, thank them again for their time, and hang up.

AT THIS TIME, SUBJECT IS ADMITTED TO THE STUDY, PENDING INFORMED CONSENT: YES NO

SCREENER NAME:

NOTE: If the potential subject passes screening and agrees to be a part of the study, they must be assigned a unique subject identification number. **Please see Study Coordinator (E. Rohn) to acquire the appropriate number in the queue.**

SUBJECT ID#: **DATE:**

CAREGIVER SUBJECT SCREENING FORM HUM68800

DEMOGRAPHICS:

SEX: Male Female

WILLING TO TRAVEL: YES NO

Use the following script when screening a potential participant.

1. As a caregiver, are you currently providing care for someone with a spinal cord injury?

Listen to their brief response.

2. Due to that person's SCI, do you assist him/her in managing their bladder and bowel functions?

Listen to their brief response.

3. Are you able to travel to Ann Arbor to meet with one of our interviewers for this study?

IF YES, skip to Question 5.

IF NO, proceed to the following.

4. We may be able to arrange for one of our interviewers to come to your home and interview you there. Would that be OK?

IF YES, proceed to the following.

IF NO, ask if there is an alternative since neither Ann Arbor nor their home seems to work for them.

5. Do you have any questions for me about the project?

Answer any questions. Once complete, ask them to hold a moment and proceed to the following page.

SUBJECT ID#: **DATE:**

CAREGIVER SUBJECT SCREENING FORM HUM68800

Address the following from your point of view.

DO NOT ASK THIS QUESTION OF THE POTENTIAL SUBJECT – SCREENER ANSWERS HIM/HERSELF:

Potential subject is currently a caregiver for someone with SCI	YES	NO
Potential subject assists that person with SCI with their bladder and bowel	YES	NO
Potential subject has the ability to express themselves regarding their experiences:	YES	NO

IF ALL ARE YES, proceed to the following.

Thank you for your time and for answering my questions. I feel you would be a good fit for our study and someone will contact you soon to set up an appointment to conduct the interview. Is the phone number I called today the best way to reach you?

Record their preferred phone number, thank them again for their time, and hang up.

IF ONE OR MORE ARE NO, proceed to the following.

Thank you for your time and for answering my questions. I would like to discuss your case with our research team. We will contact you with a decision regarding your eligibility within the next two weeks. Is the phone number I called today the best way to reach you?

Record their preferred phone number, thank them again for their time, and hang up.

AT THIS TIME, SUBJECT IS ADMITTED TO THE STUDY, PENDING INFORMED CONSENT: YES NO

SCREENER NAME:

NOTE: If the potential subject passes screening and agrees to be a part of the study, they must be assigned a unique subject identification number. **Please see Study Coordinator (E. Rohn) to acquire the appropriate number in the queue.**

RESEARCH PARTICIPANTS NEEDED

The University of Michigan is conducting a new study to learn more about how neurogenic bladder and bowel in people with spinal cord injury affect quality of life.

Who can participate in this study?

- You are between the ages of 18 and 70 years;
- You have an SCI which happened less than a year ago **OR** more than 10 years ago **OR** you are a caregiver for someone with an SCI and have been a caregiver of that person for more than 30 days;
- Able to speak and understand English.

What does the study involve?

1. A one-on-one interview over the telephone, in the clinic or in your home. This will take 60 – 90 minutes. For participants with SCI, there will also be a series of surveys to complete which will take another 60 – 80 minutes.
2. A focus group of people with SCI and caregivers about similar issues you talked about in your interview. This will take place in an accessible location in Ann Arbor and take 60 – 90 minutes.

Who do I contact to learn more?

- E-mail to the researchers at DOD-SCIStudy@umich.ued.
- Call the researchers at 734/763-6189 and mention the "DOD SCI Study"

IRBMED #HUM000068800
Principal Investigator: Denise G. Tate, Ph.D., ABPP

Oral Recruitment Script for Veterans with SCI

Use the following script when telephoning a potential participant.

Hello, my name is XXX and I am calling from the Ann Arbor VA Department of Physical Medicine and Rehabilitation. Dr. DiPonio is the principal investigator here at the VA for this study and we sent you a letter a few weeks ago about a new study. I wanted to tell you a little more about the new study and to see if you would be interested in joining. Would that be OK?

IF NO, thank them for their participation and hang up.

IF YES, proceed to the following:

We are conducting research about how neurogenic bladder and bowel in people with spinal cord injury affect quality of life and other things like mood, going out into the community and taking care of bowel and bladder dysfunction. The study is asking veterans with SCI and caregivers of someone with spinal cord injury about their experiences in managing bowel and bladder dysfunction. Would you be interested in learning more about this study?

IF NO, thank them for taking the time to hear about it and hang up.

IF YES, proceed to the following:

In this study you will do a one-on-one interview, in person here at the VA, talking in depth about issues such as the kinds of problems you experience with bowel and bladder and how these affect your independence, coping with problems, or how taking care of bowel and bladder functions affects intimate and family relationships. The interview will take 60 – 90 minutes to do. You will also complete a series of questionnaires about your mood, the quality of care you get, and you bowel and bladder program and any specific problems you may have. That should take another 60 – 80 minutes.

Does this sound like something you would be interested in doing?

IF NO, thank them and hang up.

IF YES, proceed to the following.

If you have time right now, let's set up a time for you to come to the VA and I will go over the informed consent form and answer any questions you have. When we are done with that, you will do your interview and fill out the questionnaire.

IF YES, proceed to scheduling.

IF NO, schedule a time to call back and schedule interview.

Thank you for agreeing to join this study!

Oral Recruitment Script for Caregivers

Use the following script when telephoning a potential participant.

Hello, my name is XXX and I am calling from the Ann Arbor VA Department of Physical Medicine and Rehabilitation. Dr. DiPonio is the principal investigator here at the VA for this study and we sent you a letter a few weeks ago about a new study. I wanted to tell you a little more about the new study and to see if you would be interested in joining. Would that be OK?

IF NO, thank them for their participation and hang up.

IF YES, proceed to the following:

We are conducting research about how neurogenic bladder and bowel in people with spinal cord injury affect quality of life and other things like mood, going out into the community and taking care of bowel and bladder dysfunction. The study is asking veterans with SCI and caregivers of someone with spinal cord injury about their experiences in managing bowel and bladder dysfunction. Would you be interested in learning more about this study?

IF NO, thank them for taking the time to hear about it and hang up.

IF YES, proceed to the following:

In this study you will do a one-on-one interview, in person here at the VA, talking in depth about issues such as the kinds of problems you experience with bowel and bladder and how these affect your independence, coping with problems, or how taking care of bowel and bladder functions affects intimate and family relationships. Does this sound like something you would be interested in doing?

IF NO, thank them and hang up.

IF YES, proceed to the following.

If you have time right now, let's set up a time for you to come to the VA. I will meet with you to go over the informed consent form and answer any questions you have. When we are done with that, you will do your interview with the interviewer.

IF YES, proceed to scheduling.

IF NO, schedule a time to call back and schedule interview.

Thank you for agreeing to join this study!

SUBJECT ID#: **DATE:**

SPINAL CORD INJURY SUBJECT SCREENING FORM 2013-010067

DEMOGRAPHICS (from SCI registry/medical record):

SEX: Male Female TIME SINCE INJURY:

WILLING TO TRAVEL: YES NO LEVEL OF INJURY/ASIA SCALE:

Use the following script when screening a potential participant.

1. Can you tell me about the cause of your injury?

Listen to their brief response.

2. Due to your SCI, do you have any problems with your bladder and bowel functions?

Listen to their brief response.

3. Do you have a caregiver, someone who works with you to meet at least some of your needs?

Listen to their brief response.

4. Our research study takes place at the Ann Arbor VA and you would need to meet one of our interviewers there for this study. Will you be able to meet one of us there?

IF YES, proceed to the following.

IF NO, explain to the potential subject the need to conduct all research at the VA. If the response is still "NO", thank them for their time and inform them that we cannot enroll them in the study.

5. Do you have any questions for me about the project?

Answer any questions. Once complete, ask them to hold a moment and proceed to the following page.

SUBJECT ID#: **DATE:**

SPINAL CORD INJURY SUBJECT SCREENING FORM HUM68800

Address the following from your point of view:

DO NOT ASK THIS QUESTION OF THE POTENTIAL SUBJECT – SCREENER ANSWERS HIM/HERSELF:

Potential subject has the ability to express themselves regarding their experiences: YES NO

IF YES, proceed to the following.

Thank you for your time and for answering my questions. I feel you would be a good fit for our study and someone will contact you soon to set up an appointment to conduct the interview. Is the phone number I called today the best way to reach you?

Record their preferred phone number and proceed to the following.

We have both male and female interviewers. Do you have a preference for your interview?

Circle one: Male Female No preference

Assure them that someone will be contacting them soon to schedule an interview, thank them again for their time, and hang up.

IF NO, proceed to the following.

Thank you for your time and for answering my questions. I would like to discuss your case with our research team. We will contact you with a decision regarding your eligibility within the next two weeks. Is the phone number I called today the best way to reach you?

Record their preferred phone number, thank them again for their time, and hang up.

AT THIS TIME, SUBJECT IS ADMITTED TO THE STUDY, PENDING INFORMED CONSENT: YES NO

SCREENER NAME:

NOTE: If the potential subject passes screening and agrees to be a part of the study, they must be assigned a unique subject identification number. **Please see Study Coordinator (E. Rohn) to acquire the appropriate number in the queue.**

SUBJECT ID#: **DATE:**

CAREGIVER SUBJECT SCREENING FORM 2013-010067

DEMOGRAPHICS:

SEX: Male Female

WILLING TO TRAVEL: YES NO

Use the following script when screening a potential participant.

1. As a caregiver, are you currently providing care for someone with a spinal cord injury?

Listen to their brief response.

2. Due to that person's SCI, do you assist him/her in managing their bladder and bowel functions?

Listen to their brief response.

3. Our research study takes place at the Ann Arbor VA and you would need to meet one of our interviewers there for this study. Will you be able to meet one of us there?

IF YES, proceed to the following.

IF NO, explain to the potential subject the need to conduct all research at the VA. If the response is still "NO", thank them for their time and inform them that we cannot enroll them in the study.

4. Do you have any questions for me about the project?

Answer any questions. Once complete, ask them to hold a moment and proceed to the following page.

SUBJECT ID#: **DATE:**

CAREGIVER SUBJECT SCREENING FORM HUM68800

Address the following from your point of view.

DO NOT ASK THIS QUESTION OF THE POTENTIAL SUBJECT – SCREENER ANSWERS HIM/HERSELF:

Potential subject is currently a caregiver for someone with SCI	YES	NO
Potential subject assists that person with SCI with their bladder and bowel	YES	NO
Potential subject has the ability to express themselves regarding their experiences:	YES	NO

IF ALL ARE YES, proceed to the following.

Thank you for your time and for answering my questions. I feel you would be a good fit for our study and someone will contact you soon to set up an appointment to conduct the interview. Is the phone number I called today the best way to reach you?

Record their preferred phone number, thank them again for their time, and hang up.

IF ONE OR MORE ARE NO, proceed to the following.

Thank you for your time and for answering my questions. I would like to discuss your case with our research team. We will contact you with a decision regarding your eligibility within the next two weeks. Is the phone number I called today the best way to reach you?

Record their preferred phone number, thank them again for their time, and hang up.

AT THIS TIME, SUBJECT IS ADMITTED TO THE STUDY, PENDING INFORMED CONSENT: YES NO

SCREENER NAME:

NOTE: If the potential subject passes screening and agrees to be a part of the study, they must be assigned a unique subject identification number. **Please see Study Coordinator (E. Rohn) to acquire the appropriate number in the queue.**

RESEARCH PARTICIPANTS NEEDED

The VA Ann Arbor Health System is conducting a new study to learn more about how neurogenic (or a loss of control of) bladder and bowel in people with spinal cord injury affect quality of life.

Who can participate in this study?

- Caregivers of someone with a spinal cord injury who have been a caregiver for more than 30 days;
- Between the ages of 18 and 70 years;
- Able to speak and understand English;
- And able and willing to travel the Ann Arbor VA.

What does the study involve?

A one-on-one interview at the Ann Arbor VA. This will take 60 – 90 minutes.

Who do I contact to learn more?

- E-mail to the researchers at ejrohn@med.umich.edu
- Call the researchers at (734)763-6189 and mention the “DOD SCI Study”

Principal Investigator: Lisa DiPonio, MD

Interviewer roles by study site, study population, and data collection method

This table details individual roles in data collection on the DOD project. Each role has a primary and secondary person assigned to it. It is designed to help the team members understand their roles, support one another in the work, and know who to turn to for assistance.

ALL *questionnaires are now to be administered by project staff – we've decided* ***NOT*** *to allow subjects to complete questionnaires on their own.*

A primary person will likely complete 70–100% of the data collection in their category, and the secondary person will complete the remainder.

Interviewer	UM SCI Qualitative (N=20 interviews)	UM SCI Questionnaire (N=20 questionnaires)	VA SCI Qualitative (N=20 interviews)	VA SCI Questionnaire (N=20 questionnaires)	UM Caregivers (N=10 interviews)	VA Caregivers (N=10 interviews)
Nevedal	Secondary					
Pines		Primary		Primary*	Secondary	Primary*
Rohn	Primary	Secondary	Secondary*	Secondary*		
Roller					Primary	Secondary*
Roth			Primary*			

*These data collection activities may ONLY be done after completing the VA Without Compensation (WOC) verification. This is a lengthy process and should be started as soon as possible! Go to http://www.annarbor.research.va.gov/ANNARBORRESEARCH/wocpage.asp and contact Ed for questions.

2. CONSENT & INTERVIEW PROCEDURES

1. Interviewers schedule their own interview meetings and should work together on scheduling.
    a. **NOTE**: Measures and interviews MUST be completed within two weeks of each other.
    b. The DOD Project Outlook calendar should be added to your Outlook and used to help us monitor the flow of data collection – especially in instances where two interviewers are interviewing the same person (there is a two-week deadline between qualitative and questionnaire interviews!) – **CONFIRM INTERVIEWS 1 to 2 DAYS IN ADVANCE!**

2. Qualitative Interviews MUST be conducted face-to-face, unless the you obtain prior approval.
    a. UM Subjects may be interviewed at Burlington, at the subject's home, or at their clinic – as long as quiet and confidentiality can be reasonably assured.
    b. Space at Burlington may be "booked" on the shared Outlook calendars. If you do not have access to the shared calendars, please contact the study coordinator for assistance
    c. VA Subjects MUST be interviewed at the Ann Arbor VA, in our secure interview office. Access to this office is through the Study Coordinator (Rohn), Dr. DiPonio, or Dr. Roth.
    d. Any VA activities should be communicated as soon as possible to the physicians that use that room – DiPonio, Roth, Werner. Rohn can assist in this communication.

3. Questionnaires must be completed within two weeks following the qualitative interview!
    a. UM Subjects may complete questionnaire in person at any secure location or by phone.
    b. VA Subjects MUST complete measures face-to-face in our secure interview office.

4. Prior to the interview
    a. Print the appropriate consent forms, interview guides, quantitative measures packet, response cards & compensation form. These are here below and on the shared drive.
    b. Print a second copy of the appropriate consent form for the subject to keep.
    c. Check out the proper equipment through the study coordinator, preferably the day-of.
        i. UM equipment is stored in the study coordinator's office
        ii. VA equipment is stored in our office there and CAN NOT LEAVE THE VA!

5. At the interview
    a. CONSENT MUST BE CONDUCTED PRIOR TO ANY DATA COLLECTION! Consent is conducted by the Qualitative Interviewer.
        i. Use appropriate consent form for group (SCI or Caregiver) AND site (UM or VA)
        ii. Consents MUST UTILIZE the appropriate "Informed Consent Checklist" – the VA in particular will audit these, so they MUST be completed.
    b. Conduct the qualitative interview using the appropriate Interview Guide
        i. Be sure to fill out and give the Appointment Reminder Form to the subject.
        ii. Be sure to fill out Interview Receipt document, with a copy for us and for subject
        iii. Be sure to document whether an SCI patient's Caregiver wishes to participate.
    c. Conduct the quantitative measures using the correct Questionnaire Packet and **CARDS**
        i. Ask qual interviewer to provide copy of the measures to the subject.
        ii. Measures can (and ideally should) be completed in REDCap to ease data entry.

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project: Psychosocial and Behavioral Factors Associated with Bowel and Bladder Management after SCI

Principal Investigator: Denise G. Tate, PhD, ABPP

Co-Investigators: Lisa DiPonio, M.D., Anne Pelletier-Cameron, MD, Gianna Rodriguez, MD, Randy Roth, PhD, Claire Kalpakjian, PhD, and Martin Forchheimer, MPP

GENERAL INFORMATION

We are conducting research about how neurogenic bladder and bowel in people with spinal cord injury affect quality of life and other things like mood, going out into the community and taking care of bowel and bladder dysfunction. This study is funded by the U.S. Department of Defense. The study is asking persons with spinal cord injury (civilians and veterans) and caregivers of someone with spinal cord injury about their experiences in managing bowel and bladder dysfunction. All participants will be interviewed by an experienced interviewer about their experiences. To learn more about these, we are asking people with spinal cord injury to be involved in a one-on-one interview, one focus group session and to complete questionnaires.

A total of 60 people (40 people with spinal cord injury and 20 caregivers of someone with a spinal cord injury) will participate in this research study. People who are between the ages of 18 and 70 and are able to communicate comfortably in English are eligible for this study. People with a spinal cord injury will be either within 12 months post-injury or 10 or more years post-injury.

The study will involve a **one-on-one interview,** talking in depth about issues such as the kinds of problems you experience with bowel and bladder, how it affects your independence, coping with problems, or how taking care of bowel and bladder functions affect intimate and family relationships. The interview will take 60 – 90 minutes to do and will be audio-recorded. This is because the researchers will carefully go over what you talked about during the interview. You will also complete a **series of questionnaires** about your mood, the quality of care you get, and any specific problems you have with your bowel and bladder. This will be done after you complete the interview and this should take another 45 – 60 minutes. If you prefer, you can take the questionnaires home with you and mail them back. Or someone can call you later and do it over the phone. It is your choice and should be done within two weeks from the time of the interview.

Some people who do the telephone interviews will be invited to also participate in a **focus group** which will take 60 – 90 minutes to complete. Not everyone will be invited to be in the focus group. If you are invited and choose to participate, you will sign another consent form. During the focus group, you will share your thoughts about the same kinds of issues you were interviewed about. Below are three options to choose for this study; each one is a little different so read your choices carefully. Please put your initials next to your choice (<u>you will choose only one option</u>).

- **Option 1**: I agree to be a part of the one-on-one interview and questionnaires AND, if I am selected, I also agree to be contacted about participating in the focus group. _____ *initials*
- **Option 2**: I agree to do the one-on-one interview and questionnaires ONLY. _____ *initials*
- **Option 3**: I agree to be part of the focus group ONLY. _____ *initials*

The **risks** in this study are related to privacy and confidentiality. To protect your confidentiality, during the interviews, you will not use your name or other information that will identify you. We will carefully check the transcripts from the interview recording to erase anything else that may identify you. Your name will also not be on any research paperwork. Instead, your name will be connected to an anonymous study number that will be on the paperwork. To protect your privacy, the one-on-one interviews will take place at your house, over the phone or in a private room next to the clinic. We will also need to review your medical record to find out more about your spinal cord injury treatment related to bowel and bladder care.

There are no direct benefits to you for taking part in this study. On the other hand, other people with SCI may benefit by the information we learn in terms of how to optimize treatments and reduce negative impacts on quality of life. This research is voluntary. You do not have to take part in this study. Choosing not to be in this research study will not affect your care in any way. There is no charge to you or your health insurance for being in this study. You will receive $25 after completing the interview. The University of Michigan accounting department will need your name, address, and payment amount for tax reporting purposes.

AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- All hospital records relating to your spinal cord injury, the treatment you have received, and your response to the treatment

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- As the sponsor of this research, the Department of Defense may access the research records.
- Study sponsors or funders, or safety monitors or committees, may need the information to, make sure the study is done safely and properly, or analyze the results of the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, payment amount, and related information for tax reporting purposes.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed. Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information see http://www.med.umich.edu/hipaa/npp.htm. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by contacting the researchers listed below.

Your signature in the next section means that you have received copies of all of the following documents:

☐ This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

☐ Other (specify):_____

CONTACT INFORMATION

To find out more about the study, ask a question or express a concern about the study or if you feel you have experienced any harm from the study contact one of the following:

Principal Investigator: Denise Tate, Ph.D. Mailing Address: 300 N. Ingalls, NI209, Ann Arbor, MI 48109-5491 Telephone: 734-763-0971 (Office) Study Coordinators: Andrea Nevedal, Ph.D., Edward Rohn, MA and Connie Pines Mailing Address: 300 N. Ingalls, NI209, Ann Arbor, MI 48109-5491 Telephone: 734-763-0971 (Office) Email: DOD-SCIStudy@umich.edu	
University of Michigan Compliance Help Line at 1-888-296-2481 or if you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481	University of Michigan Medical School Institutional Review Board (IRBMED) 2800 Plymouth Road Building 200, Room 2086 Ann Arbor, MI 48109-2800 734-763-4768 E-mail: irbmed@umich.edu

SIGNATURES

Research Subject:

I understand the information printed on this form. My questions so far have been answered.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID:_____ Date of Birth: _____

Legal Representative (if applicable):
Signature of Person Legally
Authorized to Give Consent_____ Date: _____

Name (Print legal name): _____ Phone: _____

Address: _____
Check Relationship to Subject:

☐Parent ☐Spouse ☐Child ☐Sibling ☐Legal Guardian ☐Other: _____

If this consent is for a child who is a ward of the state (for example a foster child), please tell the study team immediately. The researchers may need to contact the IRBMED.

Reason subject is unable to sign for self:_____

_____

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project: Psychosocial and Behavioral Factors Associated with Bowel and Bladder Management after SCI

Principal Investigator: Denise G. Tate, PhD, ABPP

Co-Investigators: Lisa DiPonio, M.D., Anne Pelletier-Cameron, MD, Gianna Rodriguez, MD, Randy Roth, PhD, Claire Kalpakjian, PhD, and Martin Forchheimer, MPP

GENERAL INFORMATION

We are conducting research about how neurogenic bladder and bowel in people with spinal cord injury affect quality of life and other things like mood, going out into the community and taking care of bowel and bladder dysfunction. This study is funded by the U.S. Department of Defense. The study is asking persons with SCI (civilians and veterans) and caregivers of someone with spinal cord injury about their experiences in managing bowel and bladder dysfunction. All participants will be interviewed by an experienced interviewer about their experiences. To learn more about these, we are asking people with spinal cord injury and caregivers to be involved in a one-on-one interview, one focus group session and to complete questionnaires.

A total of 60 people (40 people with spinal cord injury and 20 caregivers of someone with a spinal cord injury) will participate in this research study. People who are between the ages of 18 and 70 and are able to communicate comfortably in English are eligible for this study. Caregivers of someone with a spinal cord injury will have worked with someone with SCI for at least 30 days to be eligible and can be a family member or non-family member.

The study will involve a **one-on-one interview,** talking in depth about issues you experience as a caregiver of someone with a spinal cord injury, such as the kinds of problems the person you care for has with bowel and bladder, how it affects their independence, coping with problems, or how taking care of bowel and bladder functions affects relationships. The interview will take 60 – 90 minutes to do and will be audio-recorded. This is because the researchers will carefully go over what you talked about during the interview.

Some people who do the telephone interviews will also be invited to participate in a **focus group,** which will take 60 – 90 minutes to complete. Not everyone will be invited to be in a focus group. During the focus group, you will share your thoughts about the same kinds of issues you were interviewed about. If you are invited and choose to participate in the focus group, you will sign another consent form.

Below are three options to choose for this study; each one is a little different so read your choices carefully. Please put your initials next to your choice (<u>you will choose only one option</u>).

- **Option 1**: I agree to be a part of the one-on-one interview AND, if I am selected, I also agree to be contacted about participating in the focus group. _____ *initials*
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- **Option 3**: I agree to be part of the focus group ONLY. _____ *initials*

The **risks** in this study are related to privacy and confidentiality. To protect your confidentiality, during the interviews, you or the interviewer will not use your name or other information that will identify you. We will carefully check the transcripts from the interview recording to erase anything else that may identify you. Your name will also not be on any research paperwork. Instead, your name will be connected to an anonymous study number that will be on the paperwork. To protect your privacy, the one-on-one interviews will take place at your house, over the phone or in a private room next to the clinic. As the sponsor of this research, the Department of Defense may access the research records.

There are no direct benefits to you for taking part in this study. On the other hand, other people with SCI may benefit by the information we learn in terms of how to optimize treatments and reduce negative impacts on quality of life. This research is voluntary. You do not have to take part in this study. Choosing not to be in this research study will not affect your care in any way. There is no charge to you or your health insurance for being in this study. You will receive $25 after completing the interview. The University of Michigan accounting department will need your name, address, and payment amount for tax reporting purposes.

Your signature in the next section means that you have received copies of all of the following documents:

❑ This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

CONTACT INFORMATION

To find out more about the study, ask a question or express a concern about the study or if you feel you have experienced any harm from the study contact one of the following:

<table>
<tr><td colspan="2">Principal Investigator: Denise Tate, Ph.D.
Mailing Address: 300 N. Ingalls, NI209, Ann Arbor, MI 48109-5491
Telephone: 734-763-0971 (Office)

Study Coordinators: Andrea Nevedal, Ph.D., Edward Rohn, MA, Sunny Roller, M.S. and Connie Pines
Mailing Address: 300 N. Ingalls, NI209, Ann Arbor, MI 48109-5491
Telephone: 734-763-0971 (Office)
Email: DOD-SCIStudy@umich.edu</td></tr>
<tr><td>University of Michigan Compliance Help Line at 1-888-296-2481 or if you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481</td><td>University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 200, Room 2086
Ann Arbor, MI 48109-2800
734-763-4768
E-mail: irbmed@umich.edu</td></tr>
</table>

SIGNATURES

Research Subject:

I understand the information printed on this form. My questions so far have been answered.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID:_____ Date of Birth: _____

Legal Representative (if applicable):
Signature of Person Legally
Authorized to Give Consent_____ Date: _____

Name (Print legal name): _____ Phone: _____

Address: _____
Check Relationship to Subject:

☐Parent ☐Spouse ☐Child ☐Sibling ☐Legal Guardian ☐Other: _____

If this consent is for a child who is a ward of the state (for example a foster child), please tell the study team immediately. The researchers may need to contact the IRBMED.

Reason subject is unable to sign for self:_____

_____

UM

Obtaining Informed Consent Checklist *RCO 2//28/13*

>Document to be completed for each consent obtained and filed with the original informed consent document<

RESEARCH STUDY IDENTIFICATION (Required information)
STUDY TITLE: Psychological & Behavioral Factors Associated with Bowel & Bladder Management after SCI PI: Denise Tate, PhD NAME OF STUDY TEAM MEMBER OBTAINING CONSENT:_____ ROLE OF STUDY TEAM MEMBER OBTAINING CONSENT: _____

RESEARCH SUBJECT IDENTIFICATION: (Required information)

			N/A	**/ /**
Last Name	**First Name**	**Mid. Init.**	**Last-4 SSN**	**Date (mm/dd/yy)**

A.	<< Date ALL required SIGNATURES (Subject, Witness (If required by IRB) and Person Obtaining Consent), their PRINTED NAMES and the DATES they signed the informed consent document (ICD) have been checked and appear in the proper location
B.	<< Date and Time of Day (ICD) was reviewed and deemed complete and valid
C.	<< Date and Time of the subject's first study activity or involvement
	Verify and Initial each of the following 12 requirements.
1.	Informed consent and HIPPA authorization was obtained from this subject prior to study participation. Note: Recorded Date and Time of Day (ICD) was reviewed and deemed complete and valid (B.) MUST be prior to recorded Date and Time of Day Subject began study participation (C).
2.	I have been officially added to the IRB and accepted my role in the study, designating me as an authorized agent of the PI and qualified to obtain consent for this study.
3.	This prospective subject was given adequate time necessary to carefully and fully read the Informed consent document (ICD) and all questions were answered to his/her satisfaction.
4.	All aspects of this subject's study involvement, including the purpose of the study, known and potential risks, possible benefits and alternatives to study participation were explained and discussed prior to subject signing the ICD.
5. N/A	If required, an enrollment note and scanned Consent Form image will be entered in the patient's electronic medical record (CPRS).
6.	Subject has been consented using the most recently approved, UM logo date-stamped version of the appropriate consent form (SCI or Caregiver).
7.	A copy of the fully-completed signed, original informed consent document has been issued to this subject and he/she was instructed to retain that copy for reference and to ask any and all questions that might arise throughout his/her study involvement.
8.	The subject has been shown where in the ICD to locate study team phone number(s) and the phone number of the UM IRB Coordinator. The subject has been reminded to call with any questions or concerns.
9.	The subject has been informed that participation is entirely voluntary and that they may withdraw their participation at any time and for any reason.
10.	I'm aware that original ICDs and all copies must be printed and issued as single-sided documents and that the original signed ICD must be kept in the study coordinator's office.
11.	It is my opinion (person obtaining consent) and the opinion of the Principal Investigator that this subject is capable of understanding the informed consent document and what his/her overall involvement in the study will entail.
12.	I know I can contact the UM IRB Coordinator at 734.763.4768 or the Research Compliance Help Line at 1.888.296.2481 if I have questions or concerns regarding the consent of this or any individual considering study participation.

Oral Consent Elements

Read over the phone (with waiver of documentation)

For Interviews

Revised April 17, 2013

Subject Name: _____

Date provided to subject: _____

Interviewer: _____

We are conducting research about how neurogenic bladder and bowel in people with spinal cord injury affects health, quality of life and other things like mood, going out into the community and taking care of bowel and bladder dysfunction. This study is funded by the U.S. Department of Defense. The study is asking people with SCI (civilians and veterans) and caregivers of someone with spinal cord injury about their experiences in managing bowel and bladder and the associated problems.

To learn more about these, we are asking people with spinal cord injury and caregivers to be involved in a one-on-one interview, a focus group session and for those participants with SCI, to complete questionnaires.

A total of 60 people (40 people with spinal cord injury and 20 caregivers of someone with a spinal cord injury) will participate in this research study. People who are between the ages of 18 and 70 and are able to communicate comfortably in English are eligible for this study.

FOR SCI ONLY

People with a spinal cord injury will have had their SCI during the last 12 months or be 10 or more years post-injury.

The study will involve a **one-on-one interview,** talking in depth about issues such as the kinds of problems you experience with bowel and bladder, how it affects your independence, coping with problems, or how taking care of bowel and bladder functions affect intimate and family relationships. The interview will take 60 – 90 minutes to do and will be audio-recorded. This is because the researchers will carefully go over what you talked about during the interview. The one-on-one interview will take place at your house, over the phone or in a private room next to the clinic. You will also complete a **series of questionnaires** about your mood, the quality of care you get, and any specific problems you have with your bowel and bladder. This will be done after you complete the interview and this should take another 45 – 60 minutes. If you prefer, you can take the questionnaires home with you and mail them back. Or someone can call you later and do it over the phone. It is your choice and should be done within two weeks from the time of the interview.

(HIPAA Authorization)

We will also need to review your medical record to find out more about your spinal cord injury treatment related to bowel and bladder care. There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.

- The Department of Defense may request to see information about you as part of this study.
- Study sponsors or funders, or safety monitors or committees, may need the information to, make sure the study is done safely and properly, or analyze the results of the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, payment amount, and related information for tax reporting purposes.

FOR CAREGIVERS ONLY

Caregivers of someone with a spinal cord injury will have worked with someone for at least 30 days to be eligible. They can be a family member or non-family members.

The study will involve a **one-on-one interview,** talking in depth about issues you experience as a caregiver of someone with a spinal cord injury, such as the kinds of problems the person you care for has with bowel and bladder, how it affects their independence, coping with problems, or how taking care of bowel and bladder functions affects relationships. The interview will take 60 – 90 minutes to do and will be audio-recorded. This is because the researchers will carefully go over what you talked about during the interview. The one-on-one interview will take place at your house, over the phone or in a private room next to the clinic.

FOR BOTH GROUPS

Some people who do the telephone interviews will be invited to also participate in a **focus group** which will take 60 – 90 minutes to complete. Not everyone will be invited to be in the focus group. If you are invited and choose to participate, you will sign another consent form. During the focus group, you will share your thoughts about the same kinds of issues you were interviewed about.

The **risks** in this study are related to privacy and confidentiality. To protect your confidentiality, during the interviews, you will not use your name or other information that will identify you. We will carefully check the transcripts from the interview recording to erase anything else that may identify you. Your name will also not be on any research paperwork. Instead, your name will be connected to an anonymous study number that will be on the paperwork. To protect your privacy, the one-on-one interviews will take place at your house, over the phone or in a private room next to the clinic. We will also need to review your medical record to find out more about your spinal cord injury treatment related to bowel and bladder care.

There are no direct benefits to you for taking part in this study. On the other hand, other people with spinal cord injury may benefit by the information we learn in terms of how to best optimize treatments and reduce a negative impact on overall quality of life. This research is voluntary. You do not have to take part in this study.

Choosing not to be in this research study will not affect your care in any way. There is no charge to you or your health insurance for being in this study. You will receive $25 for completing the interview. The University of Michigan accounting department will need your name, address, payment amount, and related information for tax reporting purposes.

I will read three options you will choose from for this study and you will choose only one option.

- **Option 1**: I agree to be a part of the one-on-one interview (and questionnaires if I have a spinal cord injury) AND, if I am selected, I also agree to be contacted about participating in the focus group..
- **Option 2**: I agree to do the one-on-one interview ONLY (and questionnaires if I have a spinal cord injury).
- **Option 3**: I agree to be part of the focus group, if I am invited, ONLY.

Which option would you prefer? _____

Participant consents to join the study Yes No

Interviewer signature and date: _____

Title of Study:	Psychosocial and Behavioral Factors Associated with Bowel and Bladder Management after Spinal Cord Injury: VETERANS	
Principal Investigator:	Lisa DiPonio, MD	**VAMC**: VA Ann Arbor Healthcare System

PURPOSE OF RESEARCH STUDY:

We are conducting a study about how neurogenic bladder and bowel in people with spinal cord injury (SCI) affect quality of life and other things like mood, going out into the community and taking care of bowel and bladder dysfunction. The study is asking veterans with SCI and caregivers of someone with spinal cord injury about their experiences in managing bowel and bladder dysfunction.

DESCRIPTION:

This study is sponsored by the U.S. Department of Defense and being done in collaboration with the University of Michigan. People who are between the ages of 18 and 70 and are able to communicate comfortably in English are eligible for this study. People with an SCI will be either less than 12 months post-injury or 10 or more years post-injury. Veterans with SCI who receive care at the VA Ann Arbor Health Care System were invited to join this study. Twenty veterans with SCI will participate in this study. You must be able to travel to the VA to participate in the interview.

In this study, you will complete a one-on-on interview about your personal experience as a veteran with SCI. The interview will cover topics like how bowel and bladder problems affect things like quality of life, independence and community participation. The interview will take place in a private room and will take about 60 to 90 minutes. Then you will complete a set of questionnaires about your mood, the quality of care you get, and any specific problems you have with your bowel and bladder. This will be done after you complete the interview and this should take another 45 to 60 minutes. If needed, questionnaires can be completed on another day as long as it happens within one week after your interview. You can take the questionnaires home with you and mail them back or they can be completed over the telephone with the study coordinator. The total time to complete the study is about 1 hour and 45 minutes to 2 and half hours.

The one-on-one interviews will be audio-recorded and then transcribed into a document. This is because the researchers will carefully go over what you talked about to learn more about bowel and bladder and quality of life. We will also need to review your medical record to find out more about your SCI treatment related to bowel and bladder care.

We will also ask you if you know of any caregivers of people with SCI who may like to be in this study and do a one-on-one interview. You can recommend your own caregiver too. If there is someone you think might be interested you can give us their name and phone number or you can give them our contact information and they can call us. If you can't think of any caregiver that might be interested, this will not affect your participation in this study.

After your interview, if you agree, we may call you again to see if you are interested in participating in a focus group to talk more about the things you told us in your interview. Not everyone will be invited to be in the focus group. If we do invite you, we will call you back within a month after your one-on-one interview. The focus group will take place at the University of Michigan. For the focus group, about 10 other people with SCI will meet and talk about their experience, led by a group facilitator. If you are interested, we will give you contact information for the UM study team and you can call them to learn more about being in the study. If you agree to be in the focus group, you will sign a different consent form from the University of Michigan.

RESEARCH SUBJECT IDENTIFICATION: (Required information)

			| | |	/ /
Last Name	**First Name**	**Mid. Init.**	**Last-4 SSN**	**Date (mm/dd/yy)**

Title of Study:	Psychosocial and Behavioral Factors Associated with Bowel and Bladder Management after Spinal Cord Injury: VETERANS	
Principal Investigator:	Lisa DiPonio, MD	**VAMC**: VA Ann Arbor Healthcare System

Please check one of the boxes below to tell us whether it is OK to see if you are interested in learning more about a focus group.

☐ Yes, it is OK to call me

☐ No, please do not call me

RISKS:

The risks of participating in this study are very minimal. There is a risk of a loss of confidentiality of your research records. Some questions during the interview may make you uncomfortable or feel embarrassed. You may choose not to answer any question or stop the interview at any time with no penalty to you. If any questions on the surveys make you uncomfortable, you may skip them too. There may be other risks that are unforeseeable at this time.

BENEFITS:

You are not likely to directly benefit from participating in this study. On the other hand, other people with SCI may benefit by the information we learn in terms of how to optimize treatments and reduce negative impacts on quality of life.

ALTERNATE COURSES OF ACTION:

This research is voluntary. You do not have to take part in this study. Choosing not to be in this research study will not affect your care in any way and you will not lose any benefits that you may be entitled to. If you choose to end the study early, you may freely do so with no

STATEMENT OF RESEARCH RESULTS:

To protect your privacy and confidentiality, during the interviews we will ask that as much as possible, you don't use your name to say anything that identifies who you are, like where you live. But just to be sure, the person who transcribes the interview will remove anything you may have said that identifies you. Finally, we will read each transcript carefully to make sure nothing was missed that may identify you. For any study data, like a form or the transcription of your interview, your name will be connected to an anonymous study number that will be on the study paperwork. The link between your name and that number will be kept separate from the study forms. Nothing you tell us during the interview will be shared with any person outside the researchers or any other study participant. For example, if your caregiver joins the study, we will not tell them anything about what you told us and vice versa. We also will not tell you if someone you told us about joined the study.

This study is taking place in collaboration with the University of Michigan which is the lead center. Once your interview has been transcribed into a document it will be sent to the University of Michigan; the audio recording of your interview will NOT be sent. That recording will stay at the VA. The document will not contain any information that will identify who you are. Instead it will have an anonymous code number and the link between your name and that code number will stay at the VA on a protected electronic file. If you also complete the questionnaires, these too will be sent to the University of Michigan with the same code number assigned to you. Researchers at the University of Michigan will protect your data by storing paper files in locked cabinets inside locked offices; only the researchers will have a key and be able to see these files. When your data is put into a database on a computer, it will be stored on a password-protected server and only the researchers will be able to open the folder. Eventually, your data will be combined with everyone who is in this study and like you, they will all have codes to keep their information confidential.

Title of Study:	Psychosocial and Behavioral Factors Associated with Bowel and Bladder Management after Spinal Cord Injury: VETERANS	
Principal Investigator:	Lisa DiPonio, MD	**VAMC**: VA Ann Arbor Healthcare System

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law. We will let you and your physician know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study.

SPECIAL CIRCUMSTANCES:
There will be not be any costs to you for any additional care that you receive as a participant in this research study.

COMPENSATION:
When the interview and questionnaires are completed, you will receive a $25 check in the mail as thanks for your time and willingness to share you experience in this study. The University of Michigan accounting department, which will process your payment, will need your name and address. This information will be given directly to the accounting department by the study coordinator. And it will not be associated with your study information in any way. You may decline compensation if you do not want to share this information with the University of Michigan accounting department.

Title of Study:	Psychosocial and Behavioral Factors Associated with Bowel and Bladder Management after Spinal Cord Injury: VETERANS	
Principal Investigator:	Lisa DiPonio, MD	**VAMC**: VA Ann Arbor Healthcare System

RESEARCH SUBJECT'S RIGHTS:

_____ has explained this research study and answered all questions. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained. Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply for VA care and services that are not part of this study.

Participation in this study is entirely voluntary. You may refuse to participate. Refusal to participate will involve no penalty or loss of rights to which individuals are entitled. Participants may withdraw from this study at any time without penalty or loss of VA or other benefits. In the event that you sustain an injury or illness as a result of your participation in this VA approved research study, all necessary medical treatment (except in limited circumstances), will be provided in a VA medical facility. You will be treated for the injury at no cost to you. However, no additional compensation has been set aside. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

In case there are medical problems, an injury, or if you have questions, concerns or complaints about the research study, you can contact member(s) of the research study team: Edward Rohn, Study Coordinator, can be called at (734) 763-6189 during the day and Lisa DiPonio, MD can be contacted after hours at (734) 936-6266 (follow the prompts and enter Page ID# 10171).

You may contact the VA Human Studies coordinator at 734-845-3440 to ask questions about your rights as a research subject and to verify this study is reviewed and approved by the VA. You may also call when research study staff are not available or to discuss your questions or concerns with someone other than study staff. You may learn more about research at the VA Ann Arbor Healthcare System at www.annarbor.research.va.gov

I have been informed about my rights as a research subject, and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

x_____	x_____	x_____
Signature of Subject	(Print Name)	Date (mm/dd/yy)
x_____	x_____	x_____
Signature of person obtaining consent (Study personnel must be approved by VA IRB.)	(Print Name)	Date (mm/dd/yy)

IF MORE THAN ONE PAGE IS USED, EACH PAGE (VAF 10-1086) MUST BE CONSECUTIVELY NUMBERED.

Department of Veterans Affairs HIPAA Authorization Form		
Title of Study:	Psychosocial and Behavioral Factors Associated with Bowel and Bladder Management after SCI	
Principal Investigator:	Lisa DiPonio, MD	VA Ann Arbor Healthcare System

REQUEST FOR PATIENT AUTHORIZATION FOR ACCESS TO PROTECTED HEALTH INFORMATION

1. By signing this document, you authorize the Veterans Health Administration (VHA) to provide **Lisa DiPonio, MD** and the research team permission to view and collect the following Personally Identifying Information (PII) and Protected Health Information (PHI) about you for research purposes:
   -> ***Your name, where you live, your telephone number and email address.***

2. The research investigators will collect your PHI for the following specific research purposes:
   -> ***To learn about my spinal cord injury and treatment.***

3. Confidentiality Statement: The confidentiality of research records that identify you as a subject will be maintained and protected as follows :-> ***Any data collected in this study will be stored separately from any information that identifies you. We will store research data in locked cabinets in locked offices and on computers that require a password that only the study team will have.***

4. You may refuse to sign this authorization and refuse to allow the disclosure of your Protected Health Information. Your refusal will not affect your ability to receive medical care or benefits at the VA Ann Arbor Healthcare System.

5. This authorization will expire at the end of the research study.

6. This authorization may be revoked at any time by sending a written request to **Lisa DiPonio, MD, 2215 Fuller Road, Ann Arbor, 48105.** If you revoke this authorization, **Lisa DiPonio, MD** and the research team can continue to use information about you that has been collected. No information will be collected after you revoke the authorization.

7. The Ann Arbor VAMC complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. The research records from this study may be reviewed by the Institutional Review Board and Compliance Monitors of the Ann Arbor VAMC and by other government agencies (including, but not limited to: the Government Accounting Office, Office of Human Research Protections, VA Office of Inspector General and VA Office of Research Oversight). Individually-identifiable health information that may be disclosed under this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

8. **You may check any of these areas of especially sensitive information that you will allow to be disclosed to the entities in the item above.**
   [ ] Alcohol abuse treatment [ ] Drug abuse treatment [ ] Sickle Cell Anemia [ ] HIV infection

9. As part of the study, we may disclose your information to the **University of Michigan** who is coordinating this study so that we can process your subject payment. We will not share any information with these persons unless they agree to keep the information confidential and use it only for the purposes related to the study.

10. As the sponsor of this research, the Department of Defense may access the research records.

x_____[_____] x_____ x_____
Signature of Subject **Last 4-SSN** (Print Name) Date (mm/dd/yy)

x _____ leave blank if N.A. x_____ x_____
Signature of Personal Representative (Print Name) Date (mm/dd/yy)
(A Court appointed legal guardian, or a legally authorized Power of Attorney.)

Department of Veterans Affairs

CONSENT FOR USE OF PICTURE AND/OR VOICE	CONSENT OF *(Name)* ->

NOTE: The information requested on this form is solicited under the authority of title 38, United States Code. The execution of this form does not authorize disclosure of the materials specified below except for the purpose(s) stated. The specified material may be used within the VA for authorized purposes, such as for education of VA personnel or for VA research activities. It may also be disclosed outside the VA as permitted by law. If the material is part of a VA system of records, it may be disclosed outside the VA as stated in the 'Routine Uses' in the "VA Privacy Act Systems of Records" published in the Federal Register. A copy of the 'Routine Uses' is available upon request to the administrative office of the VA facility involved. You do not have to consent to have your picture or voice taken, recorded, or used. Your refusal to grant your consent will have no effect on any VA benefits to which you may be entitled.

I hereby voluntarily and without compensation authorize pictures and/or voice recording(s) to be made of me *(or of the above-name individual if the individual is legally unable to give consent)* by ***(specify the name of the VA facility, newspaper, magazine, television station, etc.)***

->During an interview conducted at the VA Ann Arbor Health System for the purposes of a research study.

While I am ***(describe the activity, if any to be photographed or recorded)***

-> Participating in a research study and doing a one-on-one interview.

I authorize disclosure of the picture and/or voice recording to ***(specify name and address of the organization, agency, or individual(s) to whom the release is to be made)***

->Researchers at the VA Ann Arbor Health System only.

I understand that the said picture, video and/or voice recording is intended for the following purpose(s):

->So that researchers can carefully review the interview and learn about my personal experiences. My voice recording will be transcribed into a text document.

I have read and understand the foregoing and I consent to the use of my picture and/or voice as specified for the above-described purpose(s). I further understand that no royalty, fee or other compensation of any character shall become payable to me by the United States for such use. I understand that consent to use my picture, video and/or voice recording is voluntary and my refusal to grant consent will have no effect on any VA benefits to which I may be entitled. I further understand that I may at any time exercise the right to cease being filmed, photographed or recorded, and may rescind my consent for up to a reasonable time before the picture, video or voice recording is used.

SIGNATURE OF INDIVIDUAL OR OTHER LEGALLY AUTHORIZED PERSON ->	DATE ->
PERMISSION OBTAINED BY *(NAME - TITLE - ADDRESS)* ->	
SIGNATURE OF INTERVIEWER OR INDIVIDUAL OBTAINING CONSENT ->	DATE ->
PRODUCTION TITLE ->	PRODUCTION NUMBER ->
INDIVIDUAL' S NAME AND ADDRESS	IMPORTANT: This form must always be completed prior to the making or using pictures, video or voice recording(s) of any VA patient. If any patient health or demographic information is to be provided or released with the picture, video or voice recording, VA Form 10-5345, Request for and Authorization to Release Medical Records or Health Information is required prior to the release of such data to any source.

VA FORM 10-3203
MAY 2005

Title of Study:	Psychosocial and Behavioral Factors Associated with Bowel and Bladder Management after Spinal Cord Injury: CAREGIVERS	
Principal Investigator:	Lisa DiPonio	**VAMC**: VA Ann Arbor Healthcare System

PURPOSE OF RESEARCH STUDY:

We are conducting a study about how neurogenic bladder and bowel in people with spinal cord injury affect quality of life and other things like mood, going out into the community and taking care of bowel and bladder dysfunction. The study is asking caregivers of someone with spinal cord injury about their experiences in managing bowel and bladder dysfunction.

DESCRIPTION:

This study is sponsored by the U.S. Department of Defense and being done in collaboration with the University of Michigan. People who are between the ages of 18 and 70 and are able to communicate comfortably in English and have been a caregiver of someone with a spinal cord injury for at least 30 days are eligible for this study. You must be able to travel to the VA to participate in the interview. You were identified as a caregiver either by a veteran with SCI that you care for or you learned about this study from a flyer or work of mouth. Ten caregivers of someone with an SCI will participate in this study.

In this study, you will complete a one-on-on interview about your personal experience as a caregiver of someone with an SCI. The interview will cover topics like how bowel and bladder problems affect things like quality of life, independence and community participation. The interview will take place in a private room at the Ann Arbor VA and will take about 60 to 90 minutes.

The one-on-one interviews will be audio-recorded and then transcribed into a document. This is because the researchers will carefully go over what you talked about to learn more about bowel and bladder and quality of life.

After your interview, if you agree, we may call you again to see if you are interested in participating in a focus group to talk more about the things you told us in your interview. Not everyone will be invited to be in the focus group. If we do invite you, we will call you back within a month after your one-on-one interview. The focus group will take place at the University of Michigan. For the focus group, about 10 other caregivers of someone with an SCI will meet to talk about their experience, led by a group facilitator. If you are interested, we will give you contact information for the UM study team and you can call them to learn more about the study. If you agree to be in the focus group, you will sign a different consent form from the University of Michigan.

Please check one of the boxes below to tell us whether it is OK to see if you are interested in learning more about a focus group.

☐ Yes, it is OK to call me

☐ No, please do not call me

RISKS:

The risks of participating in this study are very minimal. There is a risk of a loss of confidentiality of your research records. Some questions during the interview may make you uncomfortable. You may choose not to answer any question or stop the interview at any time with no penalty to you. There may be other risks that are unforeseeable at this time. Your decision whether or not to participate in this study and anything you tell us will

not be shared with anyone outside the study team. If you are a caregiver of a veteran with an SCI who is also in the study, nothing you tell us will be shared with the veteran. It is up to you whether you want to tell the person you care for if you joined the study.

BENEFITS:
You are not likely to directly benefit from participating in this study. On the other hand, other people with SCI may benefit by the information we learn in terms of how to optimize treatments and reduce negative impacts on quality of life.

ALTERNATE COURSES OF ACTION:
This research is voluntary. You do not have to take part in this study. Choosing not to be in this research study will not affect your care in any way and you will not lose any benefits that you may be entitled to. If you choose to end the study early, you may freely do so with no

STATEMENT OF RESEARCH RESULTS:
To protect your privacy and confidentiality, during the interviews we will ask that as much as possible, you don't use your name to say anything that identifies who you are, like where you live. But just to be sure, the person who transcribes the interview will remove anything you may have said that identifies you. Finally, we will read each transcript carefully to make sure nothing was missed that may identify you. For any study data, like a form or the transcription of your interview, your name will be connected to an anonymous study number that will be on the study paperwork. The link between your name and that number will be kept separate from the study forms. Nothing you tell us during the interview will be shared with any person outside the researchers or any other study participant.

This study is taking place in collaboration with the University of Michigan which is the lead center. Once your interview has been transcribed into a document it will be sent to the University of Michigan; the audio recording if your interview will NOT be sent. That recording will stay at the VA. We will send the document electronically using a secure, password protected website that only the study team can access. The document will not contain any information that will identify who you are. Instead it will have an anonymous code number and the link between your name and that code number will stay at the VA on a protected electronic file.

Researchers at the University of Michigan will protect your data by storing it on a password-protected server at the University of Michigan and only the researchers will be able to open it. Eventually, your data will be combined with everyone who is in this study and like you, they will all have codes to keep their information confidential.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law. We will let you and your physician know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study.

SPECIAL CIRCUMSTANCES:
There will be not be any costs to you for any additional care that you receive as a participant in this research study.

Title of Study:	Psychosocial and Behavioral Factors Associated with Bowel and Bladder Management after Spinal Cord Injury: CAREGIVERS

Principal Investigator:	Lisa DiPonio	**VAMC**: VA Ann Arbor Healthcare System

COMPENSATION:
When the interview is completed, you will receive a $25 check in the mail as thanks for your time and willingness to share you experience in this study. The University of Michigan accounting department which will process your payment will need your name and address. This information will be given directly to the accounting department by the study coordinator. And it will not be associated with your study information in any way. You may decline compensation if you do not want to share this information with the University of Michigan accounting department.

Department of Veterans Affairs Research Consent Form	VA AAHS Research IRB Approved 2/14/2013 Expires 2/13/2014

Title of Study:	Psychosocial and Behavioral Factors Associated with Bowel and Bladder Management after Spinal Cord Injury: CAREGIVERS	
Principal Investigator:	Lisa DiPonio	**VAMC**: VA Ann Arbor Healthcare System

RESEARCH SUBJECT'S RIGHTS:

_____ has explained this research study and answered all questions. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained. Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply for VA care and services that are not part of this study.

Participation in this study is entirely voluntary. You may refuse to participate. Refusal to participate will involve no penalty or loss of rights to which individuals are entitled. Participants may withdraw from this study at any time without penalty or loss of VA or other benefits. In the event that you sustain an injury or illness as a result of your participation in this VA approved research study, all necessary medical treatment (except in limited circumstances), will be provided in a VA medical facility. You will be treated for the injury at no cost to you. However, no additional compensation has been set aside. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

In case there are medical problems, an injury, or if you have questions, concerns or complaints about the research study, you can contact member(s) of the research study team: Edward Rohn, Study Coordinator, can be called at (734) 763-6189 during the day and Lisa DiPonio, MD can be contacted after hours at (734) 936-6266 (follow the prompts and enter Page ID# 10171).

You may contact the VA Human Studies coordinator at 734-845-3440 to ask questions about your rights as a research subject and to verify this study is reviewed and approved by the VA. You may also call when research study staff are not available or to discuss your questions or concerns with someone other than study staff. You may learn more about research at the VA Ann Arbor Healthcare System at www.annarbor.research.va.gov

I have been informed about my rights as a research subject, and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

x_____	x_____	x_____
Signature of Subject	(Print Name)	Date (mm/dd/yy)
x_____	x_____	x_____
Signature of person obtaining consent (Study personnel must be approved by VA IRB.)	(Print Name)	Date (mm/dd/yy)

IF MORE THAN ONE PAGE IS USED, EACH PAGE (VAF 10-1086) MUST BE CONSECUTIVELY NUMBERED.

Department of Veterans Affairs HIPAA Authorization Form		
Title of Study:	Double-click to enter study title here	
Principal Investigator:	Double-click to enter name of PI here	VA Ann Arbor Healthcare System

REQUEST FOR PATIENT AUTHORIZATION FOR ACCESS TO PROTECTED HEALTH INFORMATION

1. By signing this document, you authorize the Veterans Health Administration (VHA) to provide **Lisa DiPonio, MD** and the research team permission to view and collect the following Personally Identifying Information (PII) and Protected Health Information (PHI) about you for research purposes:
   -> ***Your name, where you live, your telephone number and email address***

2. The research investigators will collect your PHI for the following specific research purposes (a database?):
   -> ***The research investigators will NOT collect your PHI information.***

3. Confidentiality Statement: The confidentiality of research records that identify you as a subject will be maintained and protected as follows :-> ***Any data collected in this study will be stored separately from any information that identifies you. We will store research data in locked cabinets in locked offices and on computers that require a password that only the study team will have.***

4. You may refuse to sign this authorization and refuse to allow the disclosure of your Protected Health Information. Your refusal will not affect your ability to receive medical care or benefits at the VA Ann Arbor Healthcare System.

5. This authorization will expire at the end of the research study.

6. This authorization may be revoked at any time by sending a written request to **Lisa DiPonio, MD, 2215 Fuller Road, Ann Arbor, 48105.** If you revoke this authorization, **Lisa DiPonio, MD** and the research team can continue to use information about you that has been collected. No information will be collected after you revoke the authorization.

7. The Ann Arbor VAMC complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. The research records from this study may be reviewed by the Institutional Review Board and Compliance Monitors of the Ann Arbor VAMC and by other government agencies (including, but not limited to: the Government Accounting Office, Office of Human Research Protections, VA Office of Inspector General and VA Office of Research Oversight). Individually-identifiable health information that may be disclosed under this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

8. **You may check any of these areas of especially sensitive information that you will allow to be disclosed to the entities in the item above.**
   [ ] Alcohol abuse treatment [ ] Drug abuse treatment [ ] Sickle Cell Anemia [ ] HIV infection

9. As part of the study, we may disclose your information to the **University of Michigan** who is coordinating this study so that we can process your subject payment. We will not share any information with these persons unless they agree to keep the information confidential and use it only for the purposes related to the study.

10. As the sponsor of this research, the Department of Defense may access the research records.

x_____ Signature of Subject	[_____] **Last 4-SSN**	x_____ (Print Name)	x_____ Date (mm/dd/yy)
x _____ Signature of Personal Representative (A Court appointed legal guardian, or a legally authorized Power of Attorney.)	leave blank if N.A.	x_____ (Print Name)	x_____ Date (mm/dd/yy)

Department of Veterans Affairs

CONSENT FOR USE OF PICTURE AND/OR VOICE	CONSENT OF *(Name)* ->

NOTE: The information requested on this form is solicited under the authority of title 38, United States Code. The execution of this form does not authorize disclosure of the materials specified below except for the purpose(s) stated. The specified material may be used within the VA for authorized purposes, such as for education of VA personnel or for VA research activities. It may also be disclosed outside the VA as permitted by law. If the material is part of a VA system of records, it may be disclosed outside the VA as stated in the 'Routine Uses' in the "VA Privacy Act Systems of Records" published in the Federal Register. A copy of the 'Routine Uses' is available upon request to the administrative office of the VA facility involved. You do not have to consent to have your picture or voice taken, recorded, or used. Your refusal to grant your consent will have no effect on any VA benefits to which you may be entitled.

I hereby voluntarily and without compensation authorize pictures and/or voice recording(s) to be made of me *(or of the above-name individual if the individual is legally unable to give consent)* by ***(specify the name of the VA facility, newspaper, magazine, television station, etc.)***

-> During an interview conducted at the VA Ann Arbor Health System for the purposes of a research study.

While I am ***(describe the activity, if any to be photographed or recorded)***

-> Participating in a research study and doing a one-on-one interview.

I authorize disclosure of the picture and/or voice recording to ***(specify name and address of the organization, agency, or individual(s) to whom the release is to be made)***

-> Researchers at the VA Ann Arbor Health System only.

I understand that the said picture, video and/or voice recording is intended for the following purpose(s):

-> So that researchers can carefully review the interview and learn about my personal experiences. My voice recording will be transcribed into a document.

I have read and understand the foregoing and I consent to the use of my picture and/or voice as specified for the above-described purpose(s). I further understand that no royalty, fee or other compensation of any character shall become payable to me by the United States for such use. I understand that consent to use my picture, video and/or voice recording is voluntary and my refusal to grant consent will have no effect on any VA benefits to which I may be entitled. I further understand that I may at any time exercise the right to cease being filmed, photographed or recorded, and may rescind my consent for up to a reasonable time before the picture, video or voice recording is used.

SIGNATURE OF INDIVIDUAL OR OTHER LEGALLY AUTHORIZED PERSON ->	DATE ->
PERMISSION OBTAINED BY *(NAME - TITLE - ADDRESS)* ->	
SIGNATURE OF INTERVIEWER OR INDIVIDUAL OBTAINING CONSENT ->	DATE ->
PRODUCTION TITLE ->	PRODUCTION NUMBER ->
INDIVIDUAL' S NAME AND ADDRESS	IMPORTANT: This form must always be completed prior to the making or using pictures, video or voice recording(s) of any VA patient. If any patient health or demographic information is to be provided or released with the picture, video or voice recording, VA Form 10-5345, Request for and Authorization to Release Medical Records or Health Information is required prior to the release of such data to any source.

VA FORM 10-3203
MAY 2005

VA

Obtaining Informed Consent Checklist *RCO 2//28/13*

>Document to be completed for each consent obtained and filed with the original informed consent document<

RESEARCH STUDY IDENTIFICATION (Required information)
STUDY TITLE: Psychological & Behavioral Factors Associated with Bowel & Bladder Management after SCI PI: Lisa DiPonio, MD NAME OF STUDY TEAM MEMBER OBTAINING CONSENT:_____ ROLE OF STUDY TEAM MEMBER OBTAINING CONSENT: _____

RESEARCH SUBJECT IDENTIFICATION: (Required information)

			| | |	/ /
Last Name	**First Name**	**Mid. Init.**	**Last-4 SSN**	**Date (mm/dd/yy)**

A.	<< Date ALL required SIGNATURES (Subject, Witness (If required by IRB) and Person Obtaining Consent), their PRINTED NAMES and the DATES they signed the informed consent document (ICD) have been checked and appear in the proper location
B.	<< Date and Time of Day (ICD) was reviewed and deemed complete and valid
C.	<< Date and Time of the subject's first study activity or involvement
	Verify and Initial each of the following 12 requirements.
1.	Informed consent [and HIPAA Authorization, if required by VA-IRB] was obtained from this subject prior to study participation. Note: Recorded Date and Time of Day (ICD) was reviewed and deemed complete and valid (B.) MUST be prior to recorded Date and Time of Day Subject began study participation (C).
2.	A VA Scope of Practice Form has been signed by the PI and approved by the VA IRB which designates me as an authorized agent of the PI and qualified to obtain consent for this study.
3.	This prospective subject was given adequate time necessary to carefully and fully read the Informed consent document (ICD) and all questions were answered to his/her satisfaction.
4.	All aspects of this subject's study involvement, including the purpose of the study, known and potential risks, possible benefits and alternatives to study participation were explained and discussed prior to subject signing the ICD.
5. N/A	If required, an enrollment note and scanned Consent Form image will be entered in the patient's electronic medical record (CPRS).
6.	Subject has been consented using the most recently approved, VA logo date-stamped version of VA Form 10-1086.
7.	A copy of the fully-completed signed, original informed consent document has been issued to this subject and he/she was instructed to retain that copy for reference and to ask any and all questions that might arise throughout his/her study involvement.
8.	The subject has been shown where in the ICD to locate study team phone number(s) and the phone number of the VAAAHS IRB Coordinator. The subject has been reminded to call with any questions or concerns. Doug Feldman @ 734.845.3440
9.	The subject has been informed that participation is entirely voluntary and that they may withdraw their participation at any time and for any reason.
10.	I'm aware that original ICDs and all copies must be printed and issued as single-sided documents and that the original signed ICD must be kept in the investigator's project files on VA property.
11.	It is my opinion (person obtaining consent) and the opinion of the Principal Investigator that this subject is capable of understanding the informed consent document and what his/her overall involvement in the study will entail.
12.	I know I can contact the VAAAHS IRB Coordinator at 734.845.3440 or the Research Compliance Officer at 734.845.3766 if I have questions or concerns regarding the consent of this or any individual considering study participation.

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project: Psychosocial and Behavioral Factors Associated with Bowel and Bladder Management after SCI

Principal Investigator: Denise G. Tate, PhD, ABPP

Co-Investigators: Lisa DiPonio, M.D., Anne Pelletier-Cameron, MD, Gianna Rodriguez, MD, Randy Roth, PhD, Claire Kalpakjian, PhD, and Martin Forchheimer, MPP

GENERAL INFORMATION

We are conducting research about how neurogenic bladder and bowel in people with spinal cord injury affect quality of life and other things like mood, going out into the community and taking care of bowel and bladder dysfunction. This study is funded by the U.S. Department of Defense. The study is asking persons with spinal cord injury (civilians and veterans) and caregivers of someone with spinal cord injury about their experiences in managing bowel and bladder dysfunction. To learn more about these, we are asking people with spinal cord injury and caregivers to be involved in a focus group session.

A total of 20 people (10 people with spinal cord injury and 10 caregivers of someone with a spinal cord injury) will participate in this research study. People who are between the ages of 18 and 70 and are able to communicate comfortably in English are eligible for this study. Caregivers of someone with a spinal cord injury will have worked with someone with SCI for at least 30 days to be eligible and can be a family member or non-family member.

The study will involve a **focus group** and last 60 – 90 minutes. There will be two *separate* focus groups – one for people with spinal cord injury and one for caregivers. For the people with spinal cord injury, the discussion will be about the kinds of problems people with spinal cord injury experience with bowel and bladder problems, how it affects their independence, coping with problems, or how taking care of bowel and bladder functions affect relationships. For caregivers, the discussion will be about the experience of helping to managing bowel and bladder problems and its effect on relationships. The focus group discussions will be **audio-recorded**. This is because the researchers will carefully go over what participants talked about to learn more about bowel and bladder and quality of life.

The **risks** in this study are related to **privacy** and **confidentiality**. During the focus group, you will be talking about personal things in front of people you may or may not have met before. You are free to not say anything during any part of the discussion if you feel uncomfortable. During the discussion, we will ask you not to use your real name, but you will use a color or number to identify yourself for the audio-recording. When the recording is transcribed into a document, the researchers will carefully check to make sure there is nothing in the document that will identify you. Your name will also not be on any research paperwork. Instead, your name will be connected to an anonymous study number that will be on the paperwork. As the sponsor of this research, the Department of Defense may access the research records.

There are **no direct benefits** to you for taking part in this study. On the other hand, other people with spinal cord injury may benefit by the information we learn in terms of how to optimize treatments and reduce negative impacts on quality of life. This research is voluntary. You do not have to take part in this study. Choosing not to be in this research study will not affect your care in any way. There is no charge to you or your health insurance for being in this study. You will receive $25 after participating in the focus group. The University of Michigan accounting department will need your name, address, and payment amount for tax reporting purposes.

Your signature in the next section means that you have received copies of all of the following documents:

❑ This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

CONTACT INFORMATION

To find out more about the study, ask a question or express a concern about the study or if you feel you have experienced any harm from the study contact one of the following:

<table>
<tr><td colspan="2">Principal Investigator: Denise Tate, Ph.D.
Mailing Address: 300 N. Ingalls, NI209, Ann Arbor, MI 48109-5491
Telephone: 734-763-0971 (Office)

Study Coordinators: Andrea Nevedal, Ph.D., Edward Rohn, MA, Connie Pines and Sunny Roller, M.S.
Mailing Address: 300 N. Ingalls, NI209, Ann Arbor, MI 48109-5491
Telephone: 734-763-0971 (Office)
Email: DOD-SCIStudy@umich.edu</td></tr>
<tr><td>University of Michigan Compliance Help Line at 1-888-296-2481 or if you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481</td><td>University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 200, Room 2086
Ann Arbor, MI 48109-2800
734-763-4768
E-mail: irbmed@umich.edu</td></tr>
</table>

SIGNATURES

Research Subject:

I understand the information printed on this form. My questions so far have been answered.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID:_____ Date of Birth: _____

Legal Representative (if applicable):
Signature of Person Legally
Authorized to Give Consent_____ Date: _____

Name (Print legal name): _____ Phone: _____

Address: _____
Check Relationship to Subject:

☐Parent ☐Spouse ☐Child ☐Sibling ☐Legal Guardian ☐Other: _____

If this consent is for a child who is a ward of the state (for example a foster child), please tell the study team immediately. The researchers may need to contact the IRBMED.

Reason subject is unable to sign for self:_____

_____

Oral Consent Elements

Read over the phone (with waiver of documentation)

For Focus Groups

Revised April 17, 2013

Subject Name: _____

Date provided to subject: _____

Interviewer: _____

We are conducting research about how neurogenic bladder and bowel in people with spinal cord injury affects health, quality of life and other things like mood, going out into the community and taking care of bowel and bladder dysfunction. This study is funded by the U.S. Department of Defense. The study is asking people with SCI (civilians and veterans) and caregivers of someone with spinal cord injury about their experiences in managing bowel and bladder and the associated problems.

To learn more about these, we are asking people with spinal cord injury and caregivers to be involved in a one-on-one interview, a focus group session and for those participants with SCI, to complete questionnaires.

A total of 20 people (10 people with spinal cord injury and 10 caregivers of someone with a spinal cord injury) will participate in this research study. People who are between the ages of 18 and 70 and are able to communicate comfortably in English are eligible for this study.

FOR SCI ONLY

People with a spinal cord injury will have had their SCI during the last 12 months or be 10 or more years post-injury.

The study will involve a **focus group** and last 60 – 90 minutes. There will be two *separate* focus groups – one for people with spinal cord injury and one for caregivers. For the people with spinal cord injury, the discussion will be about the kinds of problems people with spinal cord injury experience with bowel and bladder problems, how it affects their independence, coping with problems, or how taking care of bowel and bladder functions affect relationships. For caregivers, the discussion will be about the experience of helping to managing bowel and bladder problems and its effect on relationships. The focus group discussions will be **audio-recorded**. This is because the researchers will carefully go over what participants talked about to learn more about bowel and bladder and quality of life.

(HIPAA Authorization if participating <u>ONLY</u> in the focus group; if they have participated in the one-on-one interview, do NOT read this)

We will also need to review your medical record to find out more about your spinal cord injury treatment related to bowel and bladder care. There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- The Department of Defense may request to see information about you as part of this study.

- Study sponsors or funders, or safety monitors or committees, may need the information to, make sure the study is done safely and properly, or analyze the results of the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, payment amount, and related information for tax reporting purposes.

FOR CAREGIVERS ONLY

Caregivers of someone with a spinal cord injury will have worked with someone for at least 30 days to be eligible. They can be a family member or non-family members.

The study will involve a **focus group** and last 60 – 90 minutes. There will be two *separate* focus groups – one for people with spinal cord injury and one for caregivers. For the people with spinal cord injury, the discussion will be about the kinds of problems people with spinal cord injury experience with bowel and bladder problems, how it affects their independence, coping with problems, or how taking care of bowel and bladder functions affect relationships. For caregivers, the discussion will be about the experience of helping to managing bowel and bladder problems and its effect on relationships. The focus group discussions will be **audio-recorded**. This is because the researchers will carefully go over what participants talked about to learn more about bowel and bladder and quality of life.

FOR BOTH GROUPS

The **risks** in this study are related to **privacy** and **confidentiality**. During the focus group, you will be talking about personal things in front of people you may or may not have met before. You are free to not say anything during any part of the discussion if you feel uncomfortable. During the discussion, we will ask you not to use your real name, but you will use a color or number to identify yourself for the audio-recording. When the recording is transcribed into a document, the researchers will carefully check to make sure there is nothing in the document that will identify you. Your name will also not be on any research paperwork. Instead, your name will be connected to an anonymous study number that will be on the paperwork.

There are **no direct benefits** to you for taking part in this study. On the other hand, other people with spinal cord injury may benefit by the information we learn in terms of how to optimize treatments and reduce negative impacts on quality of life. This research is voluntary. You do not have to take part in this study. Choosing not to be in this research study will not affect your care in any way. There is no charge to you or your health insurance for being in this study. You will receive $25 after participating in the focus group. The University of Michigan accounting department will need your name, address, and payment amount for tax reporting purposes.

Participant consents to join the study **Yes** **No**

Interviewer signature and date: _____

Interview Date	/ /
Participant ID	
Interviewer	

PERSON WITH SCI INTERVIEW GUIDE

INTRODUCTION: Thank you for participating in our study. We are interested in learning about your perspective and your experiences of what it's like to have to manage your bowel and bladder. We would like for you to be as honest as you can and share your true feelings. We hope that by learning about your experiences and perspectives we can learn about what it's like to live with the loss of bladder and bowel control and try help others in the future. Everything you share with me will be confidential. If you need to take a break or are feeling tired please let me know and we can stop the interview. Do you have any questions before we get started with the interview? If it is OK with you I would like to **turn on the audio recorde**r. Feel free to ask questions as we go along and share additional information that you think might be helpful for us to know about your experiences.

GUIDING CONCEPT FOR INTERVIEWERS: How has the management of and complications around bowel and bladder issues impacted the PWSCI's quality of life?

How has your care of your bowel and bladder affected your QOL? How has it affected the way you live your life?

SECTION 1: BACKGROUND INFORMATION: Before we get started with the main part of the interview I would like to learn more about you.

1) Please tell me a little bit about yourself and the circumstances surrounding your injury.

2) We find the stories people tell are a valuable way to understand people's life experiences. Please tell me your story of living with the loss of bladder and bowel function.

Probes (use if they struggle with the question):
- What is important to understand about your bladder and bowel function?
- What was it like when you realized you had bladder and bowel dysfunction?
- What were some of the biggest changes in your life when you were injured?

SECTION 2: BLADDER AND BOWEL PROGAM: Now that we've had a few minutes to talk I would like to know more about your experiences with having to manage your bladder and bowel.

GENERAL ROUTINE

1) Please describe your daily routine related to managing bladder and bowel for me.

Consider these follow-up probes for specific parts of the day/routine
Morning Routine
Afternoon Routine
Evening Routine
Bedtime Routine

2) When you leave the house (e.g., work, shopping, appointments, social events, etc), what kinds of things do you do to prepare for the trip related to bladder and bowel care?

- Do you have strategies or have to plan ahead?
- Have you had accidents or unexpected things happen?
- To what extent is being away from home difficult/problematic? Or easy?

3) To what extent has your program changed since you've been living with a spinal cord injury? [consider that people with long-term SCI might have had more changes]

INTERVIEWER: Be aware of time and redundancy; skip Section 3 if necessary.

SECTION 3: MANAGEMENT CHALLENGES & HEALTH COMPLICATIONS: The next few questions ask about challenges, problems and complications that you may have experienced related to managing your bladder and bowels.

1) What were some of the difficulties you've experienced since having to manage your bladder and bowels?

- Probes: accidents, finding proper facilities, etc.

2) What are some of the strategies you've used to deal with/resolve these difficulties?

COMPLICATIONS: For the next few questions we are interested in learning about medical complications and health issues you may have experienced related to bladder and bowel.

1) What kind of complications have you had related to your bladder?

- Health complications: UTIs, bladder/kidney stones, incontinence, leakage, sores from cathing, pain)
- Other complications

2) What kind of complications have you had related to your bowels?

- Health complications: hemorrhoids, constipation, incontinence, bloating, stomach pain, skin infection/sores.
- Other complications

3) What aspects continue to be a problem/concern for you?
4) What have you found helps you to avoid complications?

CAREGIVER/ATTENDANT RELATIONSHIP: For this next section we are interested in learning about your relationship with your caregiver. [If No caregiver, then skip these questions]

1) Do you prefer the term "caregiver" or "personal attendant/assistant"?
2) In what ways does your caregiver(s) help you manage your bladder?
3) In what ways does your caregiver(s) help you manage your bowels?
4) How do you feel about the care you receive?

- Any challenges to having someone help you with your bowel and bladder?
- What concerns, if any, do you have about the quality of the care you receive? (e.g., abuse, independence, proper care, impact complications, create challenges, helpful, provide assistance when needed)

5) How do you feel about your relationship/experience with your caregiver?

RELATIONSHIP WITH DOCTOR/HEALTH CARE PROVIDERS: This section is about your experiences with your doctor/nurse or other health care professionals that you may see for bladder and bowel care or treatment.

1) Refresh my mind – do you see the same person for bladder and bowel care? Or do you see separate health providers?

2) What do they suggest you do for bladder care?

- What do you think about these recommendations? Why or why not?
- Are they realistic for you to follow or for your situation?
- Are you able to talk to them about your concerns, questions, or modifying the program? Why or why not?

3) What do they suggest you do for bowel care?

- What do you think about these recommendations? Why or why not?
- Are they realistic for you to follow or for your situation?
- Are you able to talk to them about your concerns, questions, or modifying the program? Why or why not?

SECTION 4: SOCIAL CONSEQUENCES OF LOSS OF BLADDER AND BOWEL CONTROL: Now that we've had a chance to talk about your management routine and bladder and bowel program - I would like to learn more about how living with the loss of bladder and bowel control and how your program impacts the social aspects of your life such as relationships with other people, going out, living the life you want to live.

GENERAL RELATIONSHIPS

1) In general, to what extent has the loss of bladder and bowel control has impacted relationships with the people around you?

2) To what extent does it impact your ability to open up to others about your condition?

3) Do other people know that you experience the loss of bladder and bowel control? Why or why not?

INTIMATE/SEXUAL RELATIONSHIPS: A lot of people with SCI have mentioned that intimacy and sexuality are very important but can be challenging while living with bladder and bowel dysfunction

1) How important is sexuality and intimacy to you?

2) Have you dated or been in a relationship since your injury?

- If Yes – are you currently dating or in a relationship?
- If No – why not?

3) Can you tell me how bowel and bladder dysfunction impacts your ability to have intimate and sexual relationships?

- Probe: challenges, engage in relationship, find suitable partner
- How have you worked around or dealt with any of these issues?

4) To what extent and in what ways has bladder and bowel dysfunction impacted your physical sexual functioning?

- Probe: dexterity, lack of function, lack of sensation, body positioning
- How have you worked around or dealt with any of these issues?

5) To what extent and in what ways does neurogenic bladder and bowel impact your ability to be intimate/romantic

- Probe: fear of opening up to someone, finding a partner, dating, accidents during sexual activity, privacy
- How have you worked around or dealt with any of these issues?

FAMILY/FRIENDS - INFORMAL RELATIONSHIPS

1) To what extent has loss of bladder and bowel control impacted relationships with family or household members?

2) To what extent has loss of bladder and bowel control impacted friendships?

COMMUNITY BASED – FORMAL RELATIONSHIPS

1) How does living with the loss of bladder and bowel function impact your ability to have professional, work, community relationships?

2) To what extent has loss of bladder and bowel control impacted your ability to participate in community, social or work related activities? (e.g., work, leisure activities, church, hobbies, volunteering)?

3) Are there any activities (related to home or community life) that you would like to participate in that you do not do now? If so, please describe the barriers or challenges that you feel prevent you from participation. How do you work around these issues?

LIFE COURSE EXPECTATIONS

1) **PRESENT**: To what extent does living with bladder and bowel dysfunction impact your life goals and life expectations (e.g., how you thought you would live your life or how you want to live your life)?

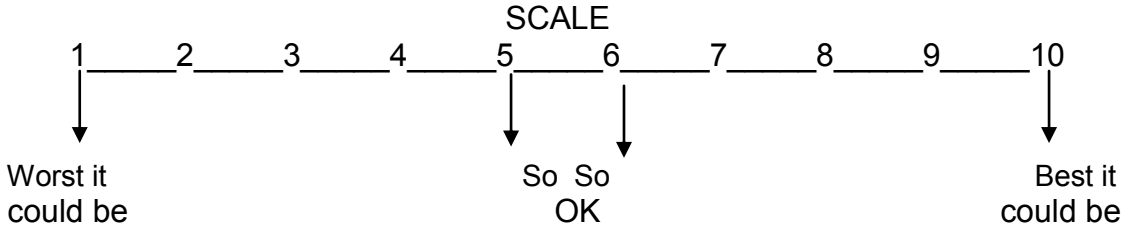
- Your ability to fulfill the roles that are important to you? (work, family relationships, spouse/partner/parent, social relationships, being independent)
- How have you worked around or dealt with any of these issues?

2) **FUTURE**: In terms of your future goals (hopes and aspirations) what do you hope to be doing, five years down the road?

3) To what extent has living with bladder and bowel impacted your sense of self?

QUALITY OF LIFE/LIFE SATISFACTION

1) This set of questions has to do with your life *right now* and how satisfied you are with the way your life is going. [SHOW SCALE] On a scale from 1-10 with 1 meaning "worst it could be" and 10 meaning "best it could be" and the middle numbers (5-6) meaning "so-so" or "OK".



2) Can you tell me why you picked that number? [Probe for details].

- What areas of your life do you find most satisfying or enjoyable? Least satisfying or enjoyable?
- What areas or aspects pertaining to quality of life (whether good or bad) are most important to you, right now?
- [if not mentioned] How big an impact does bowel dysfunction have on your quality of life? What about bladder dysfunction? Please describe.

FINAL THOUGHTS

1) What advice would you give someone else who experiences bladder and bowel complications?

2) Is there anything you wish you had known sooner?

3) IF THE SUBJECT SEEMS TO HAVE ADJUSTED WELL:

    a. You seem to have adjusted well to living with neurogenic bladder and bowel. What would say has been the secret to your success?

    b. Is there anything about you as a person that has helped you through all this?

4) IF THE SUBJECT HAS HAD DIFFICULTY ADJUSTING:

    a. You've gone through so much; do you see a way for things to improve in the future?

    b. What if anything, would improve the quality of your life?

    c. Do you feel your life will be different in five years? Why or why not?

5) Thank you for talking with me and sharing your perspective. Is there anything else that we haven't already talked about today that will help me understand your experiences with neurogenic bladder and bowel?

6) IF THEY HAVE A CAREGIVER/PERSONAL ATTENDANT:

    a. Do you think your caregiver/personal attendant would be willing to sit down with us for a similar interview?

    b. NOTE: If "yes", turn off tape recorder and collect contact information for the caregiver.

Completion Date	/ /
Participant ID	
Interviewer	

MEASURES PACKET

Please be honest and thorough as possible. Someone from our staff will contact you soon to schedule an interview to complete these questions. The interview can be in person or by phone. It must be completed within two weeks of completing the face-to-face interview. Please review these items prior to that meeting.

Thank you for being part of our study!

Personal Characteristics Form – Subjects with SCI

Gender: ___ Male ___ Female

Race: ___ Caucasian ___ African American ___ Asian ___ Other _____

Ethnicity: ___ Not Hispanic ___ Hispanic

Date of Injury: _____

Age at Injury: ____

Current Age: ____

Etiology of SCI: ___ Vehicular ___ Sports ___ Fall ___ Violence ___ Other _____

Have You Served in the U.S. Military? ___ Yes ___ No

Marital Status Currently

___ Single, Never Married ___ Married ___ Significant Other ___ Divorced
___ Separated ___ Widowed

Marital Status at Injury

___ Single, Never Married ___ Married ___ Significant Other ___ Divorced
___ Separated ___ Widowed

Current Vocational Status (Check all that apply, place an X in primary category):

___ Employed ___ Homemaker ___ Student ___ Unemployed ___ Retired - Age
___ Retired – Disability ___ Other _____

Vocational Status at Injury (Check all that apply, place an X in primary category):

___ Employed ___ Homemaker ___ Student ___ Unemployed ___ Retired
___ Other _____

Highest Level of Education Completed

___ 8^{th} grade or less ___ 9^{th}-11^{th} grade ___ High School or GED ___ Associates Degree
___ Bachelor's Degree ___ Master's Degree ___ Doctorate ___ Other _____

Living Situation (Select all that apply)

___ Live Alone ___ Live with Spouse/SO ___ Live with Parents ___ Live with Children
___ Live with Paid Caregiver ___ Live with Roommates ___ Live with Other _____

If Living with Children (Number)

___ 0 – 4 years old ___ 5-18 years old ___ Adult

Nature of Spinal Cord Injury

___ Incomplete Paraplegia ___ Complete Paraplegia

___ Incomplete Tetraplegia ___ Complete Tetraplegia

Household Income (from all sources)

___ < $25,000 ___ $25,000 - $49,999 ___ $50,000 - $74,999 ___ > $80,000

Primary Payer for Health Care

___ Auto No-Fault ___ Other Private ___ Workers' Compensation ___ Medicaire

___ Medicaid ___ Veterans Administration ___ Self Pay ___ Other _____

What is Your Primary Source of Transportation?

___ Car - Yours ___ Car – Someone Else's ___ Public Transportation

___ Other _____

Do You Have a Caregiver Who Assists you with Bowel and/or Bladder Management?

___ Yes ___ No

University of Michigan Spinal Cord Injury Model Systems
Ann Arbor, Michigan

Spinal Cord Injury Bowel and Bladder Treatment Index LT 1 Year Short Form*

Date of Data Collection: MMDDYYYY _____

Site of data collection: Clinic ___ Phone___ Other_____

Subject Identification Code: _____ Data Collector Initials: ____

Instructions to the subject: This questionnaire asks about your methods of bowel and bladder management, complications and related health and well-being issues. It includes questions about the medications that you take, symptoms and complications you may have experienced and other related issues. Let me know if you have any questions. Please note that the time of reference is not the same for all of the questions. Also, for some questions, more than one answer may be applicable.

BOWEL

A. Bowel Management Methods

1. What have been your methods of defecation and bowel care during the last 4 weeks? If you use more than one method, classify the method that you use most often as your main method and the others as supplementary methods. If you always use two methods, classify both as main methods.

	Main*	Supplementary*
Normal Defecation (require no special procedures or devices)	☐	☐
Straining/ bearing down to empty	☐	☐
Digital ano-rectal stimulation (circular stimulation of the anal canal & rectum w/ finger to assist with bowel evacuation)	☐	☐
Rectal Suppositories	☐	☐
Digital evacuation (using finger to help remove stools)	☐	☐
Enema (> 150 mL)	☐	☐
Other Flushing, e.g., Peristeen™ (using warm water from a tube placed in the rectum to stimulate the colon to release stool)	☐	☐
Colostomy (always a main method)	☐	☐
Electrical Implant to Stimulate Bowel Function	☐	☐
Oral laxatives / Medications	☐	☐
Other method _____	☐	☐

2. Has your method of bowel management changed during since your initial discharge from rehabilitation?

☐ No ☐ Yes Please explain: _____

* Adapted from the International SCI Standards and Data Sets º Adapted from NBD

** Adapted from the Coggrave Bowel Care Survey

3. <u>Since your initial discharge from rehabilitation</u>, how independent have you been with your bowel management routine?*

☐ Require total assistance ☐ Require partial assistance; does not clean self
☐ Require some assistance; clean self independently
☐ Use toilet independently but need adaptive devices or special setting (e.g. bars)
☐ Use toilet independently

4. What was the average number of <u>hours per day</u> that you spent on bowel management activities during the <u>last 4 weeks</u>? ____ Hours per day

<u>B. Complications and Symptoms</u>

5. Have you ever been bothered by any of these problems <u>since your initial discharge from rehabilitation</u>?*

☐ Hemorrhoids ☐ Sores around the anus ☐ Fissures (a crack inside the anus)
☐ Rectal Abscess (pus collects in the anal/rectal area)
☐ Rectal prolapse (the inside of the rectum turns inside out and comes out of the anus)
☐ Anal skin problems ☐ Other _____

6. Do you have chronic constipation? ☐ No ☐ Yes

7. <u>Since your initial discharge from rehabilitation</u>, how often have you had incontinence resulting in either liquid or solid stools?*

☐ Two or more times daily ☐ Daily
☐ Not every day but at least once per week
☐ Not every week but at least once per month ☐ Less than once per month
☐ Never ☐ Not Applicable

<u>C. Satisfaction and Lifestyle</u>

9. How big of an impact does bowel dysfunction have on your quality of life?*

☐ Major Impact ☐ Some Impact ☐ Little Impact ☐ No Impact

10. How satisfied are you with your bowel management routine?**

☐ Very Satisfied ☐ Satisfied ☐ Dissatisfied ☐ Very Dissatisfied

11. How flexible is your bowel management routine?** (Only read response choices if subjects ask for clarification of terms)

☐ Very flexible (I often change the time or frequency at which I manage my bowels.)
☐ Quite flexible (I can delay management or alter the timing if I want to.)
☐ Not very flexible (I don't usually change my routine unless it is unavoidable.)
☐ Not flexible at all (I will not go to activities if they clash with my bowel management time.)

* Adapted from the International SCI Standards and Data Sets º Adapted from NBD
** Adapted from the Coggrave Bowel Care Survey

BLADDER

Instructions: The following questions concern how you manage your bladder since your SCI. Please let me know if you have any questions as you answer them.

1. Are you aware of the need to empty your bladder?*

☐ No ☐ Yes ☐ Not applicable

A. Bladder Management Methods

2. What have been your methods of bladder voiding and bladder care during the last 4 weeks? If you use more than one method, classify the method that you use the most as your main method and others as supplementary ones. If you always use two methods, classify them both as main methods and any others as supplementary ones.*

	Main	Supplementary
A. Normal Voiding (voluntary initiation of urination w/o reflex stimulation or compression of the bladder)	☐	☐
B. Bladder reflex triggering		
Voluntary (tapping on bladder area, stretching to facilitate drainage)	☐	☐
Involuntary (incontinent using a diaper or condom cath; not aware of voiding)	☐	☐
C. Bladder expression		
Straining (abdominal straining, Valsalva's manoeuvre)	☐	☐
External compression (Credé manoeuvre manual pressure on the lower abdominal wall)	☐	☐
D. Intermittent catheterization (periodically inserting a cath from the urethra to the bladder to allow urine to drain)		
Self-catheterization	☐	☐
Catheterization by attendant	☐	☐
E. Indwelling catheter (catheter is housed inside the body)		
Transurethral (IC is attached to a collection bag and stays in the bladder all of the time changed weekly or less, eg, Foley. Some patients leave IC in at night and self-cath during the day)	☐	☐
Suprapubic (surgically placed, inserted through the abdomen)	☐	☐
F. Sacral anterior root stimulation (surgically implanted device that controls bladder flow)	☐	☐
G. Non-continent urinary diversion/ostomy (stoma, redirecting urine to an opening created in the abdomen)	☐	☐
H. Other method, specify_____	☐	☐

3. Do you use any collecting appliances for urinary incontinence?*

☐ No ☐ Yes, condom catheter/sheath (condom attached to a tube and collection bag)

☐ Yes, diaper/pad ☐ Yes, ostomy bag

☐ Yes, other, specify _____ ☐ Unknown

* Adapted from the International SCI Standards and Data Sets º Adapted from NBD

** Adapted from the Coggrave Bowel Care Survey

4. Has your method of bladder management changed during the time since your initial discharge from rehabilitation?

☐ No ☐ Yes Please explain:_____

5. What was the average number of hours per day that you spent on bladder management activities during the last 4 weeks? ____ Hours per day

C. Complications, Surgical Procedures and Symptoms

Urinary Tract Infections

6. How many urinary tract infections have you had since your initial discharge from rehabilitation for which you have been treated? ____

Kidney and Bladder Stones

7. Were you diagnosed with a kidney stone on an x-ray, ultrasound or CT scan since your initial discharge from rehabilitation?

☐ No ☐ Yes Number of kidney stones_____ ☐ Yes: Number unknown

8. Were you treated for bladder stones since your initial discharge from rehabilitation? (If no, skip to Question 17)

☐ No

☐ Yes: # of bladder stones ____ ☐ Yes: # unknown

Incontinence

9. Have you had any involuntary urine leakages (incontinence) since your initial discharge from rehabilitation?*

☐ Daily ☐ Not every day but at least once per week

☐ Not every week but at least once per month ☐ Less than once per month

☐ Never

10. Have you had any change in urinary symptoms since your initial discharge from rehabilitation?*

__ No __ Yes __ Not applicable

If yes please explain: _____

_____

F. Satisfaction and Lifestyle

12. How big of an impact does bladder dysfunction have on your quality of life?*

☐ Major Impact ☐ Some Impact ☐ Little Impact ☐ No Impact

13. How satisfied are you with you bladder management routine?

___ Very Satisfied ___ Satisfied ___ Dissatisfied ___ Very Dissatisfied

* Adapted from the International SCI Standards and Data Sets º Adapted from NBD

** Adapted from the Coggrave Bowel Care Survey

Behavioral Adherence Assessment of Bowel and Bladder Treatment (BAABBT)

Instructions: *This measure should be administered in interview form* by an interviewer with some basic knowledge of bowel and bladder care after SCI. It can be done by phone and/or face to face. Interviewer is encouraged to write down comments by the interviewee that may require further clarification. Complete the BAABB directly after the BBTI. For method specific questions, ask only about the pertinent methods, as determined during completion of the BBTI.

Interviewer Statement:

1) We are examining the relationship between how you manage your bowel and bladder and your health. It is important that you answer honestly and as best you can remember. This information will not be seen by your health care providers.
2) **I'm going to go through a list of recommendations that are often given for bowel and bladder management. Please tell me how often you (or someone providing you with assistance) have done these since your discharge from rehabilitation**
   - ***The responses are: Never (0%), Rarely (1 - 20% of the time); Sometime (21 - 69% of the time), Often (70 - 99 % of the time); Always (100% of the time); Not Applicable (NA)***

Bladder Management	**Performed as recommended during the last month** *never; rarely; sometimes; often; always*					
Universal bladder recommendations						
Wash hands prior to starting your bladder management program	Never	Rarely	Sometimes	Often	Always	NA
Void at least 4 times per day, with or without residual	Never	Rarely	Sometimes	Often	Always	NA
Adjust frequency and interval of voiding or catheterizations as needed	Never	Rarely	Sometimes	Often	Always	NA
Maintain supplies/equipment	Never	Rarely	Sometimes	Often	Always	NA
Adjust fluid intake as needed, drinking at least 6 cups of fluid a day.	Never	Rarely	Sometimes	Often	Always	NA
Wear appropriate gear / use appliances or supplies to keep skin dry						
• During the day	Never	Rarely	Sometimes	Often	Always	NA
• At night	Never	Rarely	Sometimes	Often	Always	NA
Take all recommended Bladder Medications						
• Forget to take prescribed medications	Never	Rarely	Sometimes	Often	Always	NA
• Choose to not take prescribed medications	Never	Rarely	Sometimes	Often	Always	NA
• Add medications or supplements on your own	Never	Rarely	Sometimes	Often	Always	NA
List _____						
Communicate with health care provider when bladder problems occur	Never	Rarely	Sometimes	Often	Always	
Suggested / optional recommendations						
Limit intake of diuretics (caffeinated and diet drinks; alcohol)	Never	Rarely	Sometimes	Often	Always	NA
Change clothes as soon as they become wet	Never	Rarely	Sometimes	Often	Always	NA
Other recommended bladder management activities						
• List _____	Never	Rarely	Sometimes	Often	Always	NA
• List _____	Never	Rarely	Sometimes	Often	Always	NA
• List _____	Never	Rarely	Sometimes	Often	Always	NA
Other activities that you regularly do for bladder management that were not recommended by your health care provider						
• List _____	Never	Rarely	Sometimes	Often	Always	NA
• List _____	Never	Rarely	Sometimes	Often	Always	NA

Bowel Management	How often did you perform this step during the last month *never; rarely; sometimes; often; always*
Universal Bowel Recommendations	
Have supplies within reach	Never Rarely Sometimes Often Always NA
Eat enough high fiber foods such as fruits and vegetables or take a fiber supplement	Never Rarely Sometimes Often Always NA
Drink at least 6 cups of fluid a day	Never Rarely Sometimes Often Always NA
Take more or less laxatives depending upon stool consistency	Never Rarely Sometimes Often Always NA
Make other adjustments to medication or diet based on stool consistency	Never Rarely Sometimes Often Always NA
Take all recommended oral Bowel Medication • Forget to take prescribed medications • Choose to not take prescribed medications • Add medications or supplements on your own List: _____	 Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA
Communicate with health care provider when having bowel related problems (such as constipation, bleeding, excessive pain, bloating)	Never Rarely Sometimes Often Always NA

Suggested / optional recommendations	
Exercise 3 times per week for 30 minutes	Never Rarely Sometimes Often Always NA
Engage in other physical activity for at least 30 minutes once per week.	Never Rarely Sometimes Often Always NA
Sit on commode or toilet during bowel movements	Never Rarely Sometimes Often Always NA
Perform bowel program 30 min to 1 hour after drinking a hot beverage or eating	Never Rarely Sometimes Often Always NA
Other recommended bowel management activities • List _____ • List _____ • List _____	 Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA
Other activities that you do for bowel management that were not recommended by your health care provider • List _____ • List _____ • List _____	 Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA

Other Health Management Activities – Regardless of whether they were recommended by a health care provider	How often did you perform this step during the last month *never; rarely; sometimes; often; always*
Used marijuana to make you feel better (If yes) For what are you using it? (If Yes) How do you intake marijuana? (If yes) On average, how much do you use? Drink cranberry juice or take cranberry supplement	No How often on average _____ Spasticity Bowel Pain Other _____ Eating (e.g. in baked goods) Smoking Vaporized Other _____ _____ Never Rarely Sometimes Often Always NA

Global Health Scale

Please respond to each item by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global01	In general, would you say your health is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02	In general, would you say your quality of life is:.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03	In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global04	In general, how would you rate your mental health, including your mood and your ability to think?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global09	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc).....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Completely	**Mostly**	**Moderately**	**A little**	**Not at all**
Global06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
Global10	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

		None	Mild	Moderate	Severe	Very severe
Global08	How would you rate your fatigue on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Global07	How would you rate your pain on average?.....	☐ 0 **No pain**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **Worst imaginable pain**

Emotional Distress – Anxiety – Short Form 8a

Please respond to each question or statement by marking one box per row.

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
EDANX01 1	I felt fearful.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX40 2	I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX41 3	My worries overwhelmed me.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX53 4	I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX46 5	I felt nervous.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX07 6	I felt like I needed help for my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX05 7	I felt anxious.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX54 8	I felt tense	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Emotional Distress – Depression – Short Form 8a

Please respond to each question or statement by marking one box per row.

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
EDDEP04 1	I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP06 2	I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP29 3	I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP41 4	I felt hopeless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP22 5	I felt like a failure	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP36 6	I felt unhappy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP05 7	I felt that I had nothing to look forward to.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP09 8	I felt that nothing could cheer me up.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Fatigue – Short Form 8a

Please respond to each question or statement by marking one box per row.

During the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
HI7 1	I feel fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
AN3 2	I have trouble <u>starting</u> things because I am tired.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

FATEXP41 3	How run-down did you feel on average? ...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP40 4	How fatigued were you on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP35 5	How much were you bothered by your fatigue on average?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP49 6	To what degree did your fatigue interfere with your physical functioning?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
FATIMP3 7	How often did you have to push yourself to get things done because of your fatigue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP16 8	How often did you have trouble finishing things because of your fatigue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Bladder Management Difficulties – Short Form

Please respond to each question or statement by marking one box per row.

	Lately…	**Not at All**	**A Little Bit**	**Somewhat**	**Quite a Bit**	**Very Much**
rToiletBL_31	I was frustrated by bladder accidents…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_5	I worried that I would have a bladder accident……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_30	Bladder accidents limited my independence…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_23	I was sad/depressed because of problems with bladder functioning……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_Com26	I worried about performing my bladder program in a public restroom…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_16	I worried about performing my bladder program……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Lately…	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
rToiletBL_76	I had bladder accidents……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_72	Bladder accidents have disrupted my daily activities…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Bladder Complications – Short Form

Please respond to each question or statement by marking one box per row.

	Lately…	**Not at All**	**A Little Bit**	**Somewhat**	**Quite a Bit**	**Very Much**
rToiletBL_21	A UTI (urinary tract infection) limited my daily activities……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_28	I had an increase in spasms because of a UTI (urinary tract infection)……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Lately…	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
rToiletBL_50	I had a urinary tract infection…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_74	I had a urinary tract infection (UTI) that would not go away…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_Com9	I avoided going out because of my urinary tract infection (UTI)…….....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Bowel – Short Form

Please respond to each question or statement by marking one box per row.

	Lately…	Not at All	A Little Bit	Somewhat	Quite a Bit	Very Much
rToiletBO_33	I was frustrated by repeated bowel accidents…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_Com25	I worried that my social activities would be interrupted by a bowel accident…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_27	I worried I would have a bowel accident...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_4	Bowel accidents limited my independence……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_7	A bowel accident has affected my self-esteem……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_29	I was upset by problems with my bowel functioning…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_12	I worried about performing my bowel program……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Lately…	Never	Rarely	Sometimes	Often	Always
rToiletBO_46	Bowel accidents have disrupted my daily activities…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_52	I had bowel accidents…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Positive Affect & Well-Being – Short Form

Please respond to each question or statement by marking one box per row.

	Lately…	Never	Rarely	Sometimes	Often	Always
PPF_30	I thought positively about my future.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF17	My life had meaning.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF20	My life had purpose.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PPF_32	I was thankful to be alive.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF12	I felt hopeful.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF19	My life was worth living.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF15	My life was satisfying.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF14	I had a sense of well-being.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF16	I had a sense of balance in my life.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF22	I felt cheerful.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF06	I looked forward with enjoyment to upcoming events.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF21	I was living life to the fullest.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF07	Many areas of my life were interesting to me.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Ability to Participate in Social Roles – Short Form

Please respond to each question or statement by marking one box per row.

	In the past 7 days…	Never	Rarely	Sometimes	Often	Always
NQPRF01	I can keep up with my family responsibilities.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF08	I am able to socialize with my friends.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF11	I can do everything for my friends that I want to do.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF32	I am able to perform my daily routines.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF34	I can keep up with my work responsibilities.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF06	I am able to do all of the family activities that I want to do.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF14	I am able to do all of the activities with friends that I want to do.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF17	I can keep up with my social commitments.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF18	I am able to do all of my regular leisure activities.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF27	I can do all the leisure activities that I want to do.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Satisfaction With Social– Short Form

Please respond to each question or statement by marking one box per row.

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
SRPSAT10	I am satisfied with my current level of social activity.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT23	I am satisfied with my ability to do leisure activities.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT25	I am satisfied with my current level of activities with my friends.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT48	I am satisfied with my ability to do things for fun at home (like reading; listening to music; etc.).	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT49	I am satisfied with my ability to perform my daily routines.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very Much
NQSAT02	I am disappointed in my ability to meet the needs of my family.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQSAT03	I am bothered by my limitations in regular family activities.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQSAT13	I am disappointed in my ability to socialize with friends.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQSAT39	I am disappointed in my ability to take care of personal and household responsibilities.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQSAT40	I am bothered by limitations in performing my work (include work at home).	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Spinal Cord Injury Lifestyle Scale

Pruitt 1998

During the last three months how often have you done the following activities?

	Never	Rarely	Sometimes	Frequently	Almost Always
Cardiovascular					
1. I avoid smoking cigarettes.	0	1	2	3	4
2. I limit the amount of fat and cholesterol in my diet (for example, I limit red meats, dairy products).	0	1	2	3	4
3. I am aware of and try to reduce my risk for heart disease.	0	1	2	3	4
4. I monitor my blood pressure on a regular basis.	0	1	2	3	4
Genitourinary					
1. I use an intermittent catheterization program and stick to the recommended schedule.	0	1	2	3	4
2. I change my catheters as often as I have been directed to.	0	1	2	3	4
3. I have episodes of bladder incontinence.	0	1	2	3	4
4. I use a rectal suppository as part of my regular bowel program.	0	1	2	3	4
Neuromusculoskeletal					
1. I do range of motion exercises daily to keep my joints flexible.	0	1	2	3	4
2. I do exercises that enhance my muscle strength (for example, weight training) at least 3 times a week.	0	1	2	3	4
3. My muscle strengthening exercises are monitored by a therapist at least once a year.	0	1	2	3	4
4. I allow my shoulder joints to rest when I am having pain from overusing them.	0	1	2	3	4
5. I do activities which put weight on the bones in my legs to help increase bone density about 3 times a week (for example, use standing frame).	0	1	2	3	4
6. I pay attention to the position my body is in when I am in my wheelchair.	0	1	2	3	4
7. I pay attention to the position my body is in when I am sleeping.	0	1	2	3	4
8. If I noticed the beginning of a contracture (a joint that is `freezing up'), I would know exactly what to do.	0	1	2	3	4

	Never	Rarely	Sometimes	Frequently	Almost Always
Skin					
1. I check my skin to look for any areas of redness or breakdown.	0	1	2	3	4
2. I do some type of pressure relief every 30 minutes any time I am in my chair or driving.	0	1	2	3	4
3. I am careful not to bump my legs, feet, or buttocks when doing transfers.	0	1	2	3	4
4. I wear something on my feet when I am out of bed (for example, shoes or foam boots).	0	1	2	3	4
5. I am careful when handling hot liquids by not carrying them in my lap.	0	1	2	3	4
6. I am aware of the condition of my wheelchair cushion.	0	1	2	3	4
7. I am aware of the condition and repair needs of my wheelchair.	0	1	2	3	4
Psychosocial					
1. I am able to get around in my house (my house is wheelchair accessible).	0	1	2	3	4
2. I am with or talk to other people at least once a day.	0	1	2	3	4

Subject ID _____ **Date _____**

Quality of Caregiving Measure

Please answer the following questions:

1. Current number of paid assistants per month _____.
2. Average number of hours of paid assistance per day _____.
3. Current number of non-paid assistants per month _____.
4. Average number of hours of non-paid (i.e. family caregiver) assistance per day _____.
5. The total number of different assistants/caregivers in the past year (12 month period) has been: _____. Do you consider this to be:

   Too many Just right Too few

6. The total number of hours of caregiver assistance that you receive per day is: _____. Do you consider this to be:

   Too much Satisfactory Too little

The following questions ask about your relationship with your primary personal care attendant/caregiver. For the purposes of this questionnaire, a primary personal attendant/caregiver will be defined as the caregiver with whom you spend the most (waking) hours per week. Is this person a paid attendant? (please circle <u>yes</u> or <u>no</u>)

1. How is communication between yourself and (name of primary personal care attendant/caregiver)-how well can you exchange ideas or talk about things that really concern you?

   Not at all well Fairly well Well Very well

2. In general, how similar are your views about life to those of (name of care recipient)?

   Not at all similar Fairly similar Similar Very similar

3. Generally, how well do you and (name of primary personal care attendant/caregiver) get along together?

   Not at all well Fairly well Well Very well

4. Taking everything into consideration, how close do you feel in the relationship between you and (name of primary personal care attendant/caregiver)?

   Not at all close Fairly close Close Very close

How important are the following to the success of your relationship with ANY personal care attendant/caregiver:

5. Your attendant's skill level

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

6. Your attendant's willingness to receive training and input regarding your care

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

7. Professionalism (on the part of the attendant/caregiver)

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

8. Your professionalism/skills as an employer

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

9. Communication

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

10. Your attendant's reliability

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

11. Mutual respect

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

12. Mutual trust

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

13. Warmth

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

14. Your attendant's respect for your privacy

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

15. Your attendant's treatment of you as a competent person

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

Please select and rank in order of importance the three most important issues from the previous list (items 1-15) with regard to your relationship with <u>any</u> personal care attendant/caregiver:

1. _____
2. _____
3. _____

Please answer the following:

1. Do you feel you need more training to act effectively as an employer of a paid personal care attendant? Circle **yes** or **no**.

Finally, please feel free to add any additional comments or concerns about personal care attendants/caregivers issues in the space below. Thank you very much.

Completion Date	/ /
Participant ID	
Interviewer	

MEASURES PACKET

Please be honest and thorough as possible. Someone from our staff will contact you soon to schedule an interview to complete these questions. The interview can be in person or by phone. It must be completed within two weeks of completing the face-to-face interview. Please review these items prior to that meeting.

Thank you for being part of our study!

Personal Characteristics Form – Subjects with SCI

Gender: ___ Male ___ Female

Race: ___ Caucasian ___ African American ___ Asian ___ Other _____

Ethnicity: ___ Not Hispanic ___ Hispanic

Date of Injury: _____

Age at Injury: ____

Current Age: ____

Etiology of SCI: ___ Vehicular ___ Sports ___ Fall ___ Violence ___ Other _____

Have You Served in the U.S. Military? ___ Yes ___ No

Marital Status Currently

___ Single, Never Married ___ Married ___ Significant Other ___ Divorced
___ Separated ___ Widowed

Marital Status at Injury

___ Single, Never Married ___ Married ___ Significant Other ___ Divorced
___ Separated ___ Widowed

Current Vocational Status (Check all that apply, place an X in primary category):

___ Employed ___ Homemaker ___ Student ___ Unemployed ___ Retired - Age
___ Retired – Disability ___ Other _____

Vocational Status at Injury (Check all that apply, place an X in primary category):

___ Employed ___ Homemaker ___ Student ___ Unemployed ___ Retired
___ Other _____

Highest Level of Education Completed

___ 8^{th} grade or less ___ 9^{th}-11^{th} grade ___ High School or GED ___ Associates Degree
___ Bachelor's Degree ___ Master's Degree ___ Doctorate ___ Other _____

Living Situation (Select all that apply)

___ Live Alone ___ Live with Spouse/SO ___ Live with Parents ___ Live with Children
___ Live with Paid Caregiver ___ Live with Roommates ___ Live with Other _____

If Living with Children (Number)

___ 0 – 4 years old ___ 5-18 years old ___ Adult

Nature of Spinal Cord Injury

___ Incomplete Paraplegia ___ Complete Paraplegia

___ Incomplete Tetraplegia ___ Complete Tetraplegia

Household Income (from all sources)

___ < $25,000 ___ $25,000 - $49,999 ___ $50,000 - $74,999 ___ > $80,000

Primary Payer for Health Care

___ Auto No-Fault ___ Other Private ___ Workers' Compensation ___ Medicaire

___ Medicaid ___ Veterans Administration ___ Self Pay ___ Other _____

What is Your Primary Source of Transportation?

___ Car - Yours ___ Car – Someone Else's ___ Public Transportation

___ Other _____

Do You Have a Caregiver Who Assists you with Bowel and/or Bladder Management?

___ Yes ___ No

University of Michigan Spinal Cord Injury Model Systems
Ann Arbor, Michigan

Spinal Cord Injury Bowel and Bladder Treatment Index Short Form (SCI-BBTI-SF)*

Date of Data Collection: MMDDYYYY _____

Site of data collection: Clinic ___ Phone___ Other_____

SCIMS Subject Identification Code: _____ Data Collector Initials: ____

Instructions to the subject: This questionnaire asks about your methods of bowel and bladder management, complications and related health and well-being issues. It includes questions about the medications that you take, symptoms and complications you may have experienced and other related issues. Let me know if you have any questions. Please note that the time of reference is not the same for all of the questions. Also, for some questions, more than one answer may be applicable.

BOWEL

A. Bowel Management Methods

1. What have been your methods of defecation and bowel care during the last 4 weeks? If you use more than one method, classify the method that you use most often as your main method and the others as supplementary methods. If you always use two methods, classify both as main methods.

	Main*	Supplementary*
Normal Defecation (require no special procedures or devices)	☐	☐
Straining/ bearing down to empty	☐	☐
Digital ano-rectal stimulation (circular stimulation of the anal canal & rectum w/ finger to assist with bowel evacuation)	☐	☐
Rectal Suppositories	☐	☐
Digital evacuation (using finger to help remove stools)	☐	☐
Enema (> 150 mL)	☐	☐
Other Flushing, e.g., Peristeen™ (using warm water from a tube placed in the rectum to stimulate the colon to release stool)	☐	☐
Colostomy (always a main method)	☐	☐
Electrical Implant to Stimulate Bowel Function	☐	☐
Oral laxatives / Medications	☐	☐
Other method _____	☐	☐

1a. If you do digital stimulation or evacuation, how frequently do you do this?*

☐ Less than once every week ☐ Once per week or more but not daily

☐ Daily ☐ Other: _____

2. Has your method of bowel management changed during the last year?

☐ No ☐ Yes Please explain: _____

* Adapted from the International SCI Standards and Data Sets º Adapted from NBD

** Adapted from the Coggrave Bowel Care Survey

3. **During the last year, how independent have you been with your bowel management routine?***
   - ☐ Require total assistance
   - ☐ Require partial assistance; does not clean self
   - ☐ Require some assistance; clean self independently
   - ☐ Use toilet independently but need adaptive devices or special setting (e.g. bars)
   - ☐ Use toilet independently

4. **What was the average number of hours per day that you spent on bowel management activities during the last 4 weeks. ___ Hours per day**

5. **On average how much time did you spend on each defecation during the last year?**
   - ☐ Less than 30 minutes
   - ☐ 31-60 minutes
   - ☐ More than an hour

6. **How often have you had a bowel movement on average during the last 4 weeks?**
   - ☐ Daily
   - ☐ 2-6 times per week
   - ☐ Less than once per week

7. **During the last year, have you experienced uneasiness, sweating or headaches during or after bowel movements?**
   - ☐ No
   - ☐ Yes

8. **Do you take medication (tablets, liquids or drops) to treat constipation?**
   - ☐ No
   - ☐ Yes:
   - ☐ tablets
   - ☐ drops or liquids

9. **Do you take medication for fecal incontinence?**
   - ☐ No
   - ☐ Yes

10. **During the last year, how often have you had episodes of gas?***
    - ☐ At least daily
    - ☐ Not every day but at least once per week
    - ☐ Not every week but at least once per month
    - ☐ Less than once per month
    - ☐ Never
    - ☐ Not Applicable – no sensation

B. Complications, Symptoms and Surgical Procedures

11. **Have you ever been bothered by any of these problems during the last year?***
    - ☐ Hemorrhoids
    - ☐ Sores around the anus
    - ☐ Fissures (a crack inside the anus)
    - ☐ Rectal Abscess (pus collects in the anal/rectal area)
    - ☐ Rectal prolapse (the inside of the rectum turns inside out and comes out of the anus)
    - ☐ Anal skin problems
    - ☐ Other _____

12. **Do you have chronic constipation?** ☐ No ☐ Yes

* Adapted from the International SCI Standards and Data Sets º Adapted from NBD
** Adapted from the Coggrave Bowel Care Survey

13. During the last year, how often have you had incontinence resulting in either liquid or solid stools?*

- ☐ Two or more times daily
- ☐ Daily
- ☐ Not every day but at least once per week
- ☐ Not every week but at least once per month
- ☐ Less than once per month
- ☐ Never
- ☐ Not Applicable

C. Satisfaction and Lifestyle

14. How big of an impact does bowel dysfunction have on your quality of life?*

☐ Major Impact ☐ Some Impact ☐ Little Impact ☐ No Impact

15. How satisfied are you with your bowel management routine?**

☐ Very Satisfied ☐ Satisfied ☐ Dissatisfied ☐ Very Dissatisfied

16. How flexible is your bowel management routine?** (Only read response choices if subjects ask for clarification of terms)

- ☐ Very flexible (I often change the time or frequency at which I manage my bowels.)
- ☐ Quite flexible (I can delay management or alter the timing if I want to.)
- ☐ Not very flexible (I don't usually change my routine unless it is unavoidable.)
- ☐ Not flexible at all (I will not go to activities if they clash with my bowel management time.)

* Adapted from the International SCI Standards and Data Sets º Adapted from NBD

** Adapted from the Coggrave Bowel Care Survey

BLADDER

Instructions: The following questions concern how you manage your bladder since your SCI. Please let me know if you have any questions as you answer them.

1. Are you aware of the need to empty your bladder?*

☐ No ☐ Yes ☐ Not applicable

A. Bladder Management Methods

2. What have been your methods of bladder voiding and bladder care during the last 4 weeks? If you use more than one method, classify the method that you use the most as your main method and others as supplementary ones. If you always use two methods, classify them both as main methods and any others as supplementary ones.*

	Main	Supplementary
A. Normal Voiding (voluntary initiation of urination w/o reflex stimulation or compression of the bladder)	☐	☐
B. Bladder reflex triggering		
Voluntary (tapping on bladder area, stretching to facilitate drainage)	☐	☐
Involuntary (incontinent using a diaper or condom cath; not aware of voiding)	☐	☐
C. Bladder expression		
Straining (abdominal straining, Valsalva's manoeuvre)	☐	☐
External compression (Credé manoeuvre manual pressure on the lower abdominal wall)	☐	☐
D. Intermittent catheterization (periodically inserting a cath from the urethra to the bladder to allow urine to drain)		
Self-catheterization	☐	☐
Catheterization by attendant	☐	☐
E. Indwelling catheter (catheter is housed inside the body)		
Transurethral (IC is attached to a collection bag and stays in the bladder all of the time changed weekly or less, eg, Foley. Some patients leave IC in at night and self-cath during the day)	☐	☐
Suprapubic (surgically placed, inserted through the abdomen)	☐	☐
F. Sacral anterior root stimulation (surgically implanted device that controls bladder flow)	☐	☐
G. Non-continent urinary diversion/ostomy (stoma, redirecting urine to an opening created in the abdomen)	☐	☐
H. Other method, specify_____	☐	☐

3. Do you use any collecting appliances for urinary incontinence?*

☐ No ☐ Yes, condom catheter/sheath (condom attached to a tube and collection bag)
☐ Yes, diaper/pad ☐ Yes, ostomy bag
☐ Yes, other, specify _____ ☐ Unknown

4. Has your method of bladder management changed during the last year?

☐ No ☐ Yes Please explain:_____

* Adapted from the International SCI Standards and Data Sets º Adapted from NBD
** Adapted from the Coggrave Bowel Care Survey

5. What was the average number of <u>hours per day</u> that you spent on bowel management activities <u>during the last 4 weeks</u>? ____ Hours per day

C. Complications, Symptoms and Surgical Procedures

Urinary Tract Infections

6. How many urinary tract infections have you had <u>during the past year</u> for which you have been treated? ____

Kidney and Bladder Stones

7. Were you diagnosed with a kidney stone on an x-ray, ultrasound or CT scan <u>during the past year</u>?

□ No □ Yes Number of kidney stones_____ □ Yes: Number unknown

8. Were you treated for bladder stones <u>during the past year</u>?

□ No □ Yes: # of bladder stones ____ □ Yes: # unknown

Incontinence

9. Have you had any involuntary urine leakages (incontinence) <u>during the last year</u>?*

☐ Daily ☐ Not every day but at least once per week
☐ Not every week but at least once per month ☐ Less than once per month
☐ Never

10. Have you had any change in urinary symptoms <u>during the last year</u>?*

__ No __ Yes __ Not applicable

If yes please explain: _____

C. Satisfaction and Lifestyle

12. How big of an impact does bladder dysfunction have on your quality of life?*

☐ Major Impact ☐ Some Impact ☐ Little Impact ☐ No Impact

13. How satisfied are you with you bladder management routine?

___ Very Satisfied ___ Satisfied ___ Dissatisfied ___ Very Dissatisfied

* Adapted from the International SCI Standards and Data Sets º Adapted from NBD
** Adapted from the Coggrave Bowel Care Survey

Behavioral Adherence Assessment of Bowel and Bladder Treatment (BAABBT)

Instructions: *This measure should be administered in interview form* by an interviewer with some basic knowledge of bowel and bladder care after SCI. It can be done by phone and/or face to face. Interviewer is encouraged to write down comments by the interviewee that may require further clarification. Complete the BAABB directly after the BBTI. For method specific questions, ask only about the pertinent methods, as determined during completion of the BBTI.

Interviewer Statement:

1) We are examining the relationship between what you do to manage your bowel and bladder and your health. It is important that you answer honestly and as best you can remember. This information will not be seen by your health care providers.
2) **I'm going to go through a list of recommendations that are often given for bowel and bladder management. Please tell me how often you (or someone providing you with assistance) have done these during the last year**
   - ***The responses are:***
     Never (0%), Rarely (1 - 20% of the time); Sometime (21 - 69% of the time), Often (70 - 99 % of the time); Always (100% of the time); Not Applicable (NA)

Bladder Management	**Performed as recommended during the last month** *never; rarely; sometimes; often; always*
Universal bladder recommendations	
Wash hands prior to starting your bladder management program	Never Rarely Sometimes Often Always NA
Void at least 4 times per day, with or without residual	Never Rarely Sometimes Often Always NA
Adjust frequency and interval of voiding or catheterizations as needed	Never Rarely Sometimes Often Always NA
Maintain supplies/equipment	Never Rarely Sometimes Often Always NA
Adjust fluid intake as needed, drinking at least 6 cups of fluid a day.	Never Rarely Sometimes Often Always NA
Wear appropriate gear / use appliances or supplies to keep skin dry • During the day • At night	 Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA
Take all recommended Bladder Medications • Forget to take prescribed medications • Choose to not take prescribed medications • Add medications or supplements on your own List _____	 Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA
Communicate with health care provider when bladder problems occur	Never Rarely Sometimes Often Always
Suggested / optional recommendations	
Limit intake of diuretics (caffeinated and diet drinks; alcohol)	Never Rarely Sometimes Often Always NA
Change clothes as soon as they become wet	Never Rarely Sometimes Often Always NA
Other recommended bladder management activities • List _____ • List _____ • List _____	 Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA
Other activities that you regularly do for bladder management that were not recommended by your health care provider • List _____ • List _____	 Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA

Bowel Management	How often did you perform this step during the last month *never; rarely; sometimes; often; always*
Universal Bowel Recommendations	
Have supplies within reach	Never Rarely Sometimes Often Always NA
Eat enough high fiber foods such as fruits and vegetables or take a fiber supplement	Never Rarely Sometimes Often Always NA
Drink at least 6 cups of fluid a day	Never Rarely Sometimes Often Always NA
Take more or less laxatives depending upon stool consistency	Never Rarely Sometimes Often Always NA
Make other adjustments to medication or diet based on stool consistency	Never Rarely Sometimes Often Always NA
Take all recommended oral Bowel Medication • Forget to take prescribed medications • Choose to not take prescribed medications • Add medications or supplements on your own List: _____	 Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA
Communicate with health care provider when having bowel related problems (such as constipation, bleeding, excessive pain, bloating)	Never Rarely Sometimes Often Always NA

Suggested / optional recommendations	
Exercise 3 times per week for 30 minutes	Never Rarely Sometimes Often Always NA
Engage in other physical activity for at least 30 minutes once per week.	Never Rarely Sometimes Often Always NA
Sit on commode or toilet during bowel movements	Never Rarely Sometimes Often Always NA
Perform bowel program 30 min to 1 hour after drinking a hot beverage or eating	Never Rarely Sometimes Often Always NA
Other recommended bowel management activities • List _____ • List _____ • List _____	 Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA
Other activities that you do for bowel management that were not recommended by your health care provider • List _____ • List _____ • List _____	 Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA Never Rarely Sometimes Often Always NA

Other Health Management Activities – Regardless of whether they were recommended by a health care provider	How often did you perform this step during the last month *never; rarely; sometimes; often; always*
Used marijuana to make you feel better (If yes) For what are you using it? (If Yes) How do you intake marijuana? (If yes) On average, how much do you use?	No How often on average _____ Spasticity Bowel Pain Other _____ Eating (e.g. in baked goods) Smoking Vaporized Other _____ _____
Drink cranberry juice or take cranberry supplement	Never Rarely Sometimes Often Always NA

Global Health Scale

Please respond to each item by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global01	In general, would you say your health is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02	In general, would you say your quality of life is:.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03	In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global04	In general, how would you rate your mental health, including your mood and your ability to think?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global09	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc).....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Completely	**Mostly**	**Moderately**	**A little**	**Not at all**
Global06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
Global10	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

		None	Mild	Moderate	Severe	Very severe
Global08	How would you rate your fatigue on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Global07	How would you rate your pain on average?.....	☐ 0 **No pain**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **Worst imaginable pain**

Emotional Distress – Anxiety – Short Form 8a

Please respond to each question or statement by marking one box per row.

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
EDANX01 1	I felt fearful.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX40 2	I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX41 3	My worries overwhelmed me.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX53 4	I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX46 5	I felt nervous.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX07 6	I felt like I needed help for my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX05 7	I felt anxious.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX54 8	I felt tense	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Emotional Distress – Depression – Short Form 8a

Please respond to each question or statement by marking one box per row.

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
EDDEP041	I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP062	I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP293	I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP414	I felt hopeless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP225	I felt like a failure	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP366	I felt unhappy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP057	I felt that I had nothing to look forward to.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP098	I felt that nothing could cheer me up.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Fatigue – Short Form 8a

Please respond to each question or statement by marking one box per row.

During the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
HI7 1	I feel fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
AN3 2	I have trouble <u>starting</u> things because I am tired.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

FATEXP41 3	How run-down did you feel on average? ...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP40 4	How fatigued were you on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP35 5	How much were you bothered by your fatigue on average?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP49 6	To what degree did your fatigue interfere with your physical functioning?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
FATIMP3 7	How often did you have to push yourself to get things done because of your fatigue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP16 8	How often did you have trouble finishing things because of your fatigue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Bladder Management Difficulties – Short Form

Please respond to each question or statement by marking one box per row.

	Lately…	**Not at All**	**A Little Bit**	**Somewhat**	**Quite a Bit**	**Very Much**
rToiletBL_31	I was frustrated by bladder accidents…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_5	I worried that I would have a bladder accident……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_30	Bladder accidents limited my independence…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_23	I was sad/depressed because of problems with bladder functioning……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_Com26	I worried about performing my bladder program in a public restroom…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_16	I worried about performing my bladder program……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Lately…	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
rToiletBL_76	I had bladder accidents……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_72	Bladder accidents have disrupted my daily activities…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Bladder Complications – Short Form

Please respond to each question or statement by marking one box per row.

	Lately…	**Not at All**	**A Little Bit**	**Somewhat**	**Quite a Bit**	**Very Much**
rToiletBL_21	A UTI (urinary tract infection) limited my daily activities……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_28	I had an increase in spasms because of a UTI (urinary tract infection)……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Lately…	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
rToiletBL_50	I had a urinary tract infection…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_74	I had a urinary tract infection (UTI) that would not go away…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBL_Com9	I avoided going out because of my urinary tract infection (UTI)…….....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Bowel – Short Form

Please respond to each question or statement by marking one box per row.

	Lately…	Not at All	A Little Bit	Somewhat	Quite a Bit	Very Much
rToiletBO_33	I was frustrated by repeated bowel accidents…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_Com25	I worried that my social activities would be interrupted by a bowel accident…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_27	I worried I would have a bowel accident...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_4	Bowel accidents limited my independence……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_7	A bowel accident has affected my self-esteem……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_29	I was upset by problems with my bowel functioning…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_12	I worried about performing my bowel program……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Lately…	Never	Rarely	Sometimes	Often	Always
rToiletBO_46	Bowel accidents have disrupted my daily activities…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
rToiletBO_52	I had bowel accidents…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Positive Affect & Well-Being – Short Form

Please respond to each question or statement by marking one box per row.

	Lately…	Never	Rarely	Sometimes	Often	Always
PPF_30	I thought positively about my future.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF17	My life had meaning.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF20	My life had purpose.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PPF_32	I was thankful to be alive.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF12	I felt hopeful.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF19	My life was worth living.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF15	My life was satisfying.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF14	I had a sense of well-being.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF16	I had a sense of balance in my life.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF22	I felt cheerful.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF06	I looked forward with enjoyment to upcoming events.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF21	I was living life to the fullest.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF07	Many areas of my life were interesting to me.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Ability to Participate in Social Roles – Short Form

Please respond to each question or statement by marking one box per row.

	In the past 7 days…	Never	Rarely	Sometimes	Often	Always
NQPRF01	I can keep up with my family responsibilities.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF08	I am able to socialize with my friends.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF11	I can do everything for my friends that I want to do.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF32	I am able to perform my daily routines.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF34	I can keep up with my work responsibilities.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF06	I am able to do all of the family activities that I want to do.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF14	I am able to do all of the activities with friends that I want to do.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF17	I can keep up with my social commitments.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF18	I am able to do all of my regular leisure activities.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPRF27	I can do all the leisure activities that I want to do.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Satisfaction With Social– Short Form

Please respond to each question or statement by marking one box per row.

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
SRPSAT10	I am satisfied with my current level of social activity.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT23	I am satisfied with my ability to do leisure activities.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT25	I am satisfied with my current level of activities with my friends.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT48	I am satisfied with my ability to do things for fun at home (like reading; listening to music; etc.).	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT49	I am satisfied with my ability to perform my daily routines.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very Much
NQSAT02	I am disappointed in my ability to meet the needs of my family.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQSAT03	I am bothered by my limitations in regular family activities.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQSAT13	I am disappointed in my ability to socialize with friends.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQSAT39	I am disappointed in my ability to take care of personal and household responsibilities.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQSAT40	I am bothered by limitations in performing my work (include work at home).	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Spinal Cord Injury Lifestyle Scale

Pruitt 1998

During the last three months how often have you done the following activities?

	Never	Rarely	Sometimes	Frequently	Almost Always
Cardiovascular					
1. I avoid smoking cigarettes.	0	1	2	3	4
2. I limit the amount of fat and cholesterol in my diet (for example, I limit red meats, dairy products).	0	1	2	3	4
3. I am aware of and try to reduce my risk for heart disease.	0	1	2	3	4
4. I monitor my blood pressure on a regular basis.	0	1	2	3	4
Genitourinary					
1. I use an intermittent catheterization program and stick to the recommended schedule.	0	1	2	3	4
2. I change my catheters as often as I have been directed to.	0	1	2	3	4
3. I have episodes of bladder incontinence.	0	1	2	3	4
4. I use a rectal suppository as part of my regular bowel program.	0	1	2	3	4
Neuromusculoskeletal					
1. I do range of motion exercises daily to keep my joints flexible.	0	1	2	3	4
2. I do exercises that enhance my muscle strength (for example, weight training) at least 3 times a week.	0	1	2	3	4
3. My muscle strengthening exercises are monitored by a therapist at least once a year.	0	1	2	3	4
4. I allow my shoulder joints to rest when I am having pain from overusing them.	0	1	2	3	4
5. I do activities which put weight on the bones in my legs to help increase bone density about 3 times a week (for example, use standing frame).	0	1	2	3	4
6. I pay attention to the position my body is in when I am in my wheelchair.	0	1	2	3	4
7. I pay attention to the position my body is in when I am sleeping.	0	1	2	3	4
8. If I noticed the beginning of a contracture (a joint that is `freezing up'), I would know exactly what to do.	0	1	2	3	4

	Never	Rarely	Sometimes	Frequently	Almost Always
Skin					
1. I check my skin to look for any areas of redness or breakdown.	0	1	2	3	4
2. I do some type of pressure relief every 30 minutes any time I am in my chair or driving.	0	1	2	3	4
3. I am careful not to bump my legs, feet, or buttocks when doing transfers.	0	1	2	3	4
4. I wear something on my feet when I am out of bed (for example, shoes or foam boots).	0	1	2	3	4
5. I am careful when handling hot liquids by not carrying them in my lap.	0	1	2	3	4
6. I am aware of the condition of my wheelchair cushion.	0	1	2	3	4
7. I am aware of the condition and repair needs of my wheelchair.	0	1	2	3	4
Psychosocial					
1. I am able to get around in my house (my house is wheelchair accessible).	0	1	2	3	4
2. I am with or talk to other people at least once a day.	0	1	2	3	4

Subject ID _____ **Date _____**

Quality of Caregiving Measure

Please answer the following questions:

1. Current number of paid assistants per month _____.
2. Average number of hours of paid assistance per day _____.
3. Current number of non-paid assistants per month _____.
4. Average number of hours of non-paid (i.e. family caregiver) assistance per day _____.
5. The total number of different assistants/caregivers in the past year (12 month period) has been: _____. Do you consider this to be:

   Too many Just right Too few

6. The total number of hours of caregiver assistance that you receive per day is: _____. Do you consider this to be:

   Too much Satisfactory Too little

The following questions ask about your relationship with your primary personal care attendant/caregiver. For the purposes of this questionnaire, a primary personal attendant/caregiver will be defined as the caregiver with whom you spend the most (waking) hours per week. Is this person a paid attendant? (please circle <u>yes</u> or <u>no</u>)

1. How is communication between yourself and (name of primary personal care attendant/caregiver)-how well can you exchange ideas or talk about things that really concern you?

   Not at all well Fairly well Well Very well

2. In general, how similar are your views about life to those of (name of care recipient)?

   Not at all similar Fairly similar Similar Very similar

3. Generally, how well do you and (name of primary personal care attendant/caregiver) get along together?

   Not at all well Fairly well Well Very well

4. Taking everything into consideration, how close do you feel in the relationship between you and (name of primary personal care attendant/caregiver)?

   Not at all close Fairly close Close Very close

How important are the following to the success of your relationship with ANY personal care attendant/caregiver:

5. Your attendant's skill level

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

6. Your attendant's willingness to receive training and input regarding your care

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

7. Professionalism (on the part of the attendant/caregiver)

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

8. Your professionalism/skills as an employer

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

9. Communication

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

10. Your attendant's reliability

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

11. Mutual respect

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

12. Mutual trust

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

13. Warmth

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

14. Your attendant's respect for your privacy

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

15. Your attendant's treatment of you as a competent person

Very important *Somewhat important* *Somewhat unimportant* *Very unimportant*

Please select and rank in order of importance the three most important issues from the previous list (items 1-15) with regard to your relationship with <u>any</u> personal care attendant/caregiver:

1. _____
2. _____
3. _____

Please answer the following:

1. Do you feel you need more training to act effectively as an employer of a paid personal care attendant? Circle **yes** or **no**.

Finally, please feel free to add any additional comments or concerns about personal care attendants/caregivers issues in the space below. Thank you very much.

BBTI 1a

Once every week

More then once a week

Daily

Other

Unknown

BBTI 5

Less than 30 minutes

31-60 minutes

More than an hour

BBTI 10

- At least daily
- Not every day but at least once per week
- Not every week but at least once per month
- Less than once per month
- Never
- N/A – no sensation

BBTI 3

- **Total assistance**
- **Partial assistance:** do not clean self
- **Some assistance:** clean self
- **Use toilet independently:** need adaptive equipment or special setting
- **Use toilet independently**

BBTI 6

Daily

2-6 times per week

Less than once per week

BBTI 14

Major impact

Some impact

Little impact

No impact

BBTI 16

- **Very flexible** (I often change time/frequency of program)
- **Quite flexible** (I can delay management or alter timing if I want to)
- **Not very flexible** (I don't usually change my routine unless it is unavoidable)
- **Not flexible at all** (I will not go to activities if they clash w/my bowel management time)

BBTI 11

Hemorrhoids

Sores around the anus

Fissures

Rectal abscess

Rectal prolapse

Anal skin problems

Other

BBTI 13

- Two or more times daily
- Daily
- Not every day but at least once per week
- Not every week but at least once per month
- Less than once per month
- Never
- NA

BBTI 15

Very satisfied

Satisfied

Dissatisfied

Very dissatisfied

BBTI 7

- Two or more times daily
- Daily
- 1-6 times per week
- 3-4 times per month
- Never
- NA (no sensation)

BAABBT 1

- Never (0%)
- Rarely (1 – 20% of the time)
- Sometimes (21 – 69% of the time)
- Often (70 – 99% of the time)
- Always (100% of the time)
- Not Applicable (NA)

PROMIS 1

Excellent

Very Good

Good

Fair

Poor

PROMIS 3

None

Mild

Moderate

Severe

Very severe

SCI-QOL 1

Not at All

A Little Bit

Somewhat

Quite a Bit

Very Much

SCI-QOL 2

Never

Rarely

Sometimes

Frequently

Almost always

PROMIS 2

Never

Rarely

Sometimes

Often

Always

QOC

Very important

Somewhat important

Somewhat unimportant

Very unimportant

University of Michigan Health System

Psychosocial and Behavioral Factors Associated with Bladder and Bowel Management after SCI

Study ID# HUM00068800

Thank you for your participation! Please feel free to contact us anytime at the contact information below with questions or concerns.

Edward J. Rohn, Study Coordinator
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ejrohn@med.umich.edu

Constance Pines, Interviewer
Office: (734)763-0534
canewman@med.umich.edu

Dr. Andrea Nevedal, Interviewer
Office: (734)763-0623
anevedal@med.umich.edu

Your Upcoming Appointment

Your telephone interview will take approximately one hour. Please have the response cards in front of you for your appointment. The telephone interview needs to be within two weeks of your face-to-face interview. Both appointments are listed below.

Face-to-face Interview: _____

Day Date Time Completed?

Telephone Interview: _____

Day Date Time Completed?

Interview Date	/ /
Participant ID	
Interviewer	

CAREGIVER INTERVIEW GUIDE

INTRODUCTION: Thank you for participating in our study. We are interested in learning about your perspective and your experiences providing care to a person with SCI who needs help managing his/her bladder and bowel. We would like for you to be as honest as you can and share your true feelings. We hope that by learning about your experiences and perspectives on caregiving will provide insight into what it is like to care for individuals with neurogenic bowel and bladder and try help others in the future. Be assured that your responses will be treated as confidential. If you need to take a break, let me know and we can stop the interview. Do you have any questions before we get started with the interview? If it is OK with you I would like to **turn on the audio recorde**r. Feel free to ask questions as we go along and share additional information that you think might be helpful for us to know about your experiences.

GUIDING CONCEPT FOR INTERVIEWERS: How has the management of and complications around bowel and bladder issues impacted the PWSCI's quality of life?

How has caring for someone with bowel and bladder complications affected your QOL? How has it affected the way you live your life?

SECTION 1: BACKGROUND INFORMATION: I would like to begin this interview by asking you to tell me a little bit about the person you care for and how you became (his or her) caregiver?

1) Are you the only person providing SCI care to this person?

2) [If not a relative] Did you have a prior relationship with the person you are caring for? If YES, please describe.

SECTION 2: SCI CAREGIVER ACTIVITIES: I would like to know more about you day-to-day caregiving activities. Just briefly describe the tasks you typically do.

1) Let's begin with those tasks that you *routinely* perform throughout the day (or during your shift). [PROBE: If useful, use the caregiver list to guide the conversation]

Caregiving Tasks in the Home
Morning tasks
Afternoon tasks
Evening tasks
Bedtime tasks

Caregiver Tasks

- ☐ Feeding
- ☐ Dressing
- ☐ Bathing
- ☐ Bowel care
- ☐ Bladder care
- ☐ Medications
- ☐ Meal prep
- ☐ Laundry
- ☐ Housekeeping

1) Are there other caregiving tasks that you routinely do – but not on a daily basis? If so, briefly describe these activities.

2) Do you have caregiving responsibilities that take place outside the home (such as medical or therapy appointment)? (If YES, please describe briefly)

SECTION 3: BOWEL AND BLADDER MANAGEMENT ACTIVITIES: We interested in learning more about your experiences providing assistance with regard to bowel and bladder management activities.

1) What are the various ways you provide assistance with bowel/bladder management activities?

Consider not only ~~h~~ands on" assistance but any other activities directly or indirectly related to your caregiver role—e.g. laundry, meal planning, administering medications, ordering supplies etc.

2) Has the person you care for encountered any major *medical complications* related to neurogenic bladder/bowel that needed treatment and follow-up? If YES, please provide some details, including treatment/follow-up of symptoms?

3) Has the person you care for experienced any *emotional distress* associated with SCI that causes you some concern? If YES, provide some details?

Consider the following: anxiety, frustration, depression, resentment, or other behavioral factors that adherence to bowel and bladder regimen.

4) How difficult is it for you to do the tasks related to bowel/bladder management? Are there other tasks related to SCI caregiving that are not easy for you to do?

5) In your estimation, what things would make your job as a caregiver easier (or more rewarding?)

6) To whom do you turn to when you have questions or concerns about the health and welfare of the person you care for? How helpful were the people/agencies you consulted.

> Consider *informal resources* (family and friends) and as well as *formal resources* (such as physicians and other health care personal, medical supply houses, and health informational resources).

SECTION 4: Impact or SCI caregiving on family roles and community involvement: This section focuses more specifically on the impact of SCI caregiving on your family roles and your participation in the community.

1. [If caring for a family member] Has taking on the role of caregiver changed your relationship to the person to whom you provide care? If so, how (or in what way), has your relationship changed? What about your relationship to other family members?

2. Has taking on the role of caregiver changed the nature of your involvement in community-based roles? If so, how has your roles changed?

> Consider SCI caregiver's prior roles as employee, student, and/or volunteer roles in the community.

SECTION 5: SCI CAREGIVER STRESS: As a caregiver, what are some of the major challenges (stressors) associated with caring for a person with bladder and bowel dysfunction?

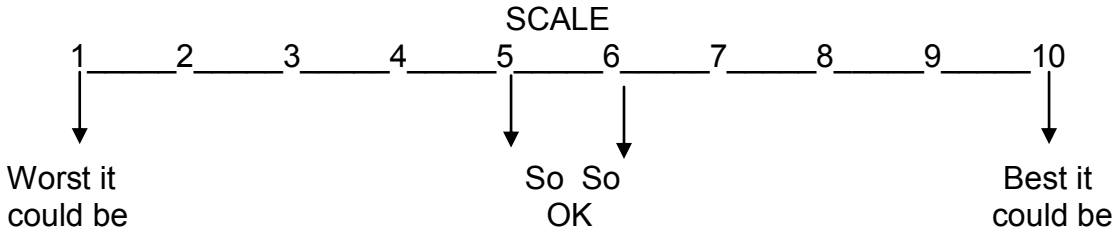
1) What do you consider to be the most significant source(s) of caregiver stress? What other issues/situations also cause you a fair amount stress?

> Consider the following stressors associated with caregiving: role conflict/role strain; economic issues; medical/behavioral issues affecting the care recipient; health provider issues; other issues.

2) What concerns, if any, do you have about the quality of and accessibility of facilities in the community, especially as this relates a person with bladder and bowel dysfunction?

SECTION 6: LIFE SATISFACTION: We are approaching the end of the interview. This last section focuses on the impact of your role as caregiver on your own quality of life (or life satisfaction).

1) This set of questions has to do with your life *right now* and how satisfied you are with the way your life is going. [SHOW SCALE] On a scale from 1-10 with 1 meaning "worst it could be" and 10 meaning "best it could be" and the middle numbers (5-6) meaning "so so" or "OK".



2) Do you feel that being a caregiver has had an impact on your physical health? If YES, please describe how caregiving has impacted (either positively or negatively) your physical health?

3) Do you feel that being a caregiver has had an impact on your emotional well-being? [If YES, please describe how caregiving has impacted (either positively or negatively on your emotional wellbeing.

4) What, if anything, would improve the quality of your life or enhance your life satisfaction?

5) Do you foresee a time in the future when you may *not be* able to continue to provide caregiving services? If so, please describe further.

6) Are there any other issues that you would like to comment on?

***Thank you very much for your time and interest in participating in our study.**

Personal Characteristics Form – Caregivers

Gender: ___ Male ___ Female

Race: ___ Caucasian ___ African American ___ Asian ___ Other _____

Ethnicity: ___ Not Hispanic ___ Hispanic

Current Age: ____

Current Marital Status

___ Single ___ Married ___ Significant Other ___ Divorced

___ Separated ___ Widowed

Highest Level of Education Completed

___ 8th grade or less ___ 9th-11th grade ___ High School or GED

___ Associates Degree ___ Bachelors Degree ___ Post Graduate Degree

___ Other _____

Living Situation (Select all that apply)

___ Live Alone ___ Live with Spouse/SO ___ Live with Care Recipient

___ Live with Other _____

Type of Caregiver: ___ Family Member

___ Unpaid family member ___ Paid family member

___ Spouse ___ Parent ___ Child ___ Other _____

___ Home Health Agency employee ___ Independent contractor

___ Other Paid _____ ___ Other Unpaid _____

Do you provide Caregiver Services to more than one person, currently? ___ Yes ___ No

(If yes) Home many hours per week do you provide Caregiver Services across all of your clients? ___ Hours

How long have been providing Caregiver Services to the person discussed during this interview?

___ Years

If you have provided Caregiver Services other than to this person, how long have you been doing this overall?: ___ Years

Impairment of Care Recipient: ___ Paraplegia ___ Tetraplegia

___ Complete ___ Incomplete

Do you provide assistance with bowel and/or bladder management? ___ Yes ___ No

(If caregiver is paid) What is your annual income from serving as a Caregiver?

___ < $10,000 ___ $10,000 - $19,999 ___ $20,000 - $34,999 ___ > $35,000

What is your annual household income, from all sources?

___ < $25,000 ___ $25,000 - $49,999 ___ $50,000 - $74,999 ___ > $80,000

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Psychosocial and Behavioral Factors Associated with Bladder and Bowel Management after SCI

INTERVIEW COMPENSATION FORM

Date: _____

Name: _____

Address:

_____

_____

Signature: _____

Interviewer: _____

3. POST INTERVIEW & DATA MANAGEMENT PROCEDURES

1. Following Qualitative Interview
    a. UM subjects:
        i. Upload audio file from the digital recorder to the shared drive (DoD Project 2012\Interview Audio Files).
        ii. Rename file UM-XXX (as appropriate where XXX = assigned Subject ID#).
        iii. Label analog tape with Subject ID#, date, and tape number (1 of 3, for example).
        iv. Return all equipment, forms, and analog tape to the Study Coordinator (Rohn).
    b. VA subjects:
        i. Upload audio file from the digital recorder to the secure VA drive (TBD).
        ii. Rename file VA-XXX (as appropriate where XXX = assigned Subject ID#).
        iii. Label analog tape with Subject ID#, date, and tape number (1 of 3, for example).
        iv. Return all equipment, forms, and analog tape to secure cabinet in the VA office.
        v. Study coordinator will periodically sort and file materials at the VA.

2. Following Questionnaire Interview
    a. UM Subjects:
        i. All responses should have been entered into REDCap as they are conducted.
        ii. If this wasn't the case, enter data into appropriate REDCap documents by ID#.
    b. VA Subjects:
        i. All responses should have been entered into REDCap as they are conducted.
        ii. If this wasn't the case, enter data into appropriate REDCap documents by ID#.

3. In all cases, interviewers should coordinate to send a <u>THANK YOU NOTE</u> to the participant. Both the qualitative interviewer and the questionnaire interviewer can sign one note and send it. Notes are available through the study coordinator, and I will leave some at the VA.

4. After all these steps:
    a. Study coordinator will process a payment with HSIP.
    b. For UM interviews, study coordinator will upload audio files for transcription.
    c. For VA interviews, study coordinator will inform approved transcriptionist that files are waiting on the secure VA server.

5. In either case, when the transcripts return, the <u>INTERVIEWER IS RESPONSIBLE FOR READING THE TRANSCRIPT AND CONDUCTING A QUALITY CHECK</u>.
    a. Study coordinator (Rohn) will contact the interviewer when the transcript returns.
    b. Check for accuracy, missing/poorly transcribed sections of speak, and overall format.
    c. When complete, mark in REDCap tracking form that it is complete (TBD).
    d. Any problems, bring them to the study coordinator (Rohn).